UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH DAKOTA

UNITED STATES OF AMERICA

and

Ex Rel. C. Dustin Bechtold, M.D.
1210 W. 18th Street
Sioux Falls, SD 57104

and

Ex. Rel. Bryan Wellman, M.D.
1210 W. 18th Street
Sioux Falls, SD 57104

Plaintiffs,

v.

Wilson Asfora, M.D.
1210 W. 18th Street
Sioux Falls, SD 57104

and

Sanford Health
1305 W 18th Street
Sioux Falls, SD 57105-0401

Serve: Kim J. Patrick
1305 W 18th Street
Sioux Falls, SD 57105-0401

and

Case No. 16-4115
FILED UNDER SEAL
Pursuant to 31 U.S.C. §3730
(False Claims Act)

DO NOT ENTER IN PACER
DO NOT PLACE IN PRESS BOX

Sanford Clinic
1305 W 18th Street
Sioux Falls, SD 57105-0401

Serve: Kim J. Patrick
1305 W 18th Street
Sioux Falls, SD 57105-0401

and

Medical Designs, LLC
6709 S. Minnesota Ave., Ste. 204
Sioux Falls, SD 57108

Serve: Brett A. Lovrien
200 E. 10th Street, Ste. 200
Sioux Falls, SD 57104

Defendants.

REDACTEDCOMPLAINT AND DEMAND FOR JURY TRIAL

1. This is a civil action by Relators Dustin Bechtold, M.D. and Bryan Wellman, M.D., by and through undersigned counsel, who file this False Claims Act ("FCA") Complaint on behalf of themselves and the United States of America against Defendants Sanford Health, Sanford Clinic, Wilson Asfora, M.D. and Medical Designs, LLC for damages and civil penalties arising out of Defendants' violations of the Federal False Claims Act, 31 U.S.C. §§3729-3733 *et seq*. and the Federal Anti-Kickback Statute related to causing improper payments from Medicare, Medicaid, and other federally and state-funded government healthcare programs.

2. This is an action for money damages, including treble damages and civil penalties, on behalf of the United States of America under the Federal False Claims Act, 31 U.S.C. §§3729-33 (FCA), Anti-Kickback Statute, 42 U.S.C. §1320a-7b, and the Food, Drug

and Cosmetic Act, 21 U.S.C. §§301-397 ("FDCA") arising from false and/or fraudulent statements, records, and claims caused to be made by the Defendants for their intentional:

(a) submission and/or causing the submission of false claims for services;

(b) performing unreasonable and medically unnecessary procedures and using devices in an off-label manner in those surgeries for the benefit of the doctor-manufacturer;

(c) fraudulent and improper billing and coding;

(d) misrepresentations to the FDA and others;

(e) falsification of medical records;

(f) the systematic violation of the Federal Anti-Kickback statute; and

(g) for sustaining a fraudulent course of conduct to obtain improper and unlawful government reimbursement and payments, all in violation of the FCA.

3. At all times, Defendant Dr. Asfora committed the fraud detailed herein and Sanford Health and Sanford Clinic (referred to collectively herein as "Sanford") management were aware of, permitted, actively encouraged, and financially benefitted from it.

4. Defendants collectively engaged in the fraud detailed herein for their own personal and financial benefit, and to the risk of patient care.

5. Defendants knew the Federal government would ultimately pay the claims for Dr. Asfora's surgeries. Sanford also knew that it was fraudulently certifying compliance with anti-kickback laws on such government submission as cost reports, as a condition of payment, and that the kickbacks at issue here would cause the certifications and cost reports to be false. Therefore, Sanford is also liable under the FCA for submitting or for knowingly causing others to submit false certifications of compliance with the AKS and for submitting false claims to get government funds paid or approved by the United States.

6. Further, despite knowing that millions of dollars in payments from the Federal government have been received in violation of the Stark statute's prohibition on receipt of payment for services rendered despite an improper financial arrangement, Defendants have failed to refund these payments as required by the Stark statute. Under the False Claims Act, 31 U.S.C. § 3729(a)(l)(G), this constitutes a knowing and improper avoidance of an obligation to transmit money to the government.

7. Upon information and belief, Sanford has made many millions from the kickback tainted Asfora devices, his improper PA billing practices and his medically unnecessary and not indicated surgeries.

8. As a direct result of Defendants' fraudulent practices as detailed herein, the Federal Treasury has been damaged in a substantial amount that is yet to be determined, but currently estimated at many millions of dollars.

9. Before filing suit, Relators and others reported the allegations contained herein to Sanford management at every level and over a long period of time. Relators have reported the fraud specifically over the last two years, including to the: President of Sanford Clinic, President of Sanford Medical Center, Executive Vice President Sanford Clinic, Chief of Staff, Chief Medical Officer and Chief Compliance Officer.

10. In an attempt to stop the fraud and patient risk and harm through internal means, Relators also participated in a formal Peer Review process which attempted to investigate and recommended discipline (termination) of Dr. Asfora to end the fraudulent practices detailed herein. They have demanded that select, particularly egregious cases of medically unnecessary and harmful procedures be sent outside for independent peer review.

11. With every report by the Relators, however, Sanford Health ignored the reports, failed to conduct a thorough investigation to conclusion, failed to discipline Dr. Asfora, failed to advise the affected patients, and failed to report medically unnecessary procedures, wrongful coding and overpayment to government payors.

12. In addition, reports and complaints by Relators and others were routinely met with intimidation and threatened discipline for the person reporting the fraud. Given the responses to their complaints, culture of tolerance and encouragement of the fraud, and the abject refusal to stop the fraudulent practices and patient harm, Relators saw no other option but to report the fraud to the Government as a last resort.

PARTIES AND ENTITIES

13. The United States, through the Department of Health and Human Services ("HHS") and, HHS's Centers for Medicare and Medicaid Services ("CMS"), is the real party-plaintiff in interest in this action. HHS's headquarters are located at 200 Independence Avenue S.W., Washington, D.C., 20201. CMS's main office is located at 7500 Security Boulevard, Baltimore, MD 21244. Plaintiff-Relator Dustin Bechtold, M.D. is a resident of South Dakota. His regular work address is 1210 W. 18th Street, Sioux Falls, SD 57104. Relator Bechtold received his Doctor of Medicine from the Creighton University School of Medicine in 2003. He is licensed in South Dakota and Minnesota and is Board Certified by the American Board of Orthopedic Surgery. He is an orthopedic surgeon specializing in hip and knee replacement surgery and hip fracture surgery. Following a fellowship in Adult Reconstruction-Lower Extremity at the Mayo Clinic in Rochester, Minnesota in 2008-2009, Dr. Bechtold joined Sanford Health in 2009. He serves as the Co-Medical Director of Hip & Knee Replacement and Hip Fracture Programs at Sanford Hospital.

14. Plaintiff-Relator Bryan Wellman, M.D. is also a resident of South Dakota. His regular work address is 1210 W. 18th Street, Sioux Falls, SD 57104. Relator Wellman received his Doctor of Medicine from the University of Pennsylvania in 1993. He is licensed in South Dakota. He was Board Certified in 1994 by the National Board of Medical Examiners and in 2002 by the American Board of Neurological Surgeons. Dr. Wellman is a neurosurgeon. Dr. Wellman joined Sanford Health in 2006.

15. Defendant Sanford Health is a South Dakota domestic nonprofit corporation incorporated in 1997 with a principal place of business in Sioux Falls. Sanford Health is a privately held company, whose chief benefactor has been Denny Sanford, who gifted $400 million in 2007 to Sanford Health—reported at the time as the largest donation ever to a health care organization. Sanford Health is a large, integrated health system serving the Dakotas. It claims to have 43 medical centers, 242 clinics, 22 long-term care facilities, 1400 physicians and to employ 27,000 within the system. Sanford is run by a 15-member Board of Trustees, on which CEO Kelby Krabbenhoft also serves. At all times relevant hereto, Sanford Health employed Dr. Asfora, encouraged his conduct and protected him. Further, Dr. Asfora was Sanford's agent and was acting within the scope of his employment,

16. Sanford Clinic is a domestic nonprofit entity organized under the laws of South Dakota and with a principal place of business in Sioux Falls.

17. Medical Designs, LLC is a domestic LLC organized under the laws of South Dakota in 1999 and with a principal place of business in Sioux Falls. According to its 2015 state filing, the Managers of Medical Designs, LLC are Wilson Asfora and Rose Asfora. Upon information and belief, Dr. Asfora has 100% ownership and control of Medical Designs. The company designs, manufactures and markets medical devices, currently touting the Asfora

Bullet Cage System, the SambaScrew System, the Dakota Knife, the Odontoid Curved Drill Guide and the Asfora Anterior Cervical Plate System.

18. Dr. Wilson Asfora is a neurosurgeon currently practicing at the Sanford Neurosurgery and Spine Clinic. Dr. Asfora joined Sanford Health in 2007. Prior to 2007, he was an independent neurosurgeon who worked at both Sanford Medical Center and Avera Health. He joined Sanford Clinic after separating from Avera Health in 2006. He is board certified in South Dakota. He is also the sole owner of Defendant Medical Designs, LLC.

JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 31 U.S.C. §3732. 31 U.S.C. §3732 specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.

20. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), because it authorizes nationwide service of process and because the Defendant has minimum contacts with the United States. Moreover, the Defendants reside in, can each be found in, and regularly transact business in South Dakota.

FCA SUBJECT MATTER JURISDICTION

21. Upon information and belief, none of the subject matter or other jurisdictional bars set forth in the FCA is applicable to this action.

22. Prior to any "public disclosure" (as defined by the FCA) and prior to filing this action, Relators voluntarily disclosed to the United States Attorney's Office for the District of South Dakota on May 2, 2016 and on August 4, 2016 the information on which the allegations or transactions in this complaint are based.

23. Through their employment at Sanford and work with Dr. Asfora, Relators are an "original source" of the information on which these allegations are based, within the meaning of the FCA.

FACTS COMMON TO ALL COUNTS

FDA Regulation of Medical Devices

24. The FDA is an agency of the United States Government responsible for protecting the health and safety of the public by assuring, among other things, that medical devices intended for use in the treatment of humans are safe and effective for their intended uses and that the labeling of such devices bear true and accurate information.

25. Pursuant to its statutory mandate, the FDA regulates the manufacture, labeling, and shipment in interstate commerce of medical devices.

26. Under the Federal Food, Drug and Cosmetic Act (Title 21, United States Code, §§301-397, the "FDCA"), and pursuant to Title 21, United States Code § 321(h), the term "device" includes "an. . . implant . . . or other similar or related article. . . which is … intended for use in. . . the treatment or prevention of disease of man... or intended to affect the structure or any function of the body of man. . . which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

27. The FDA is charged with protecting American consumers by enforcing the FDCA of 1938, the FDA Modernization Act of 1997 and related public health laws. Under the FDCA, the FDA has the responsibility of ensuring that medical devices are safe and effective before they can be marketed within the United States. The FDA's authority to regulate medical devices arises in part from the FDCA, as amended by the Medical Devices Act of 1976 ("the

1976 Amendments"). General statutory standards for determining the safety and effectiveness of devices are set forth in the FDCA, 21 U.S.C. §§360c(a)(2) and (a)(3). These standards are implemented by regulations set forth at 21 C.F.R. §860.7.

28. Under Federal law, medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type.

29. The U.S. FDA classifies medical devices based on the risks associated with a particular device. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. Class II devices are higher risk devices and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by FDA before they are marketed.

30. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval.

31. To market a Class II device, manufacturers are typically required to submit a 510(k) Premarket Notification to the FDA, unless the device is determined to be exempt from the 510(k) requirements.

32. In submitting a 510(k), the manufacturer must demonstrate that the device is at least as safe and effective (*i.e.* that the device is "substantially equivalent") to a legally marketed device (21 C.F.R. 807.92(a)(3) ("predicate device")). A legally marketed device, as described in 21 C.F.R. 807.92(a)(3), is a device that was legally marketed prior to May 28,

1976; a device which has been reclassified from Class III to Class II or I by the FDA; or a device which has already been found substantially equivalent through the 510(k) process.

33. A device is substantially equivalent if, in comparison to a legally marketed device, it: (1) has the same intended use; and (2) has the same technological characteristics as the legally marketed device OR has different technological characteristics and the manufacturer submits information to the FDA which does not raise new questions of safety or effectiveness and/or demonstrates that the device is as safe and effective as the legally marketed device.

34. For Class II medical devices requiring Premarket Notification, the manufacturer may not proceed to market the device in the United States until the manufacturer receives an order from the FDA declaring a device to be "substantially equivalent" to a predicate device.

35. Premarket Notifications are governed largely by 21 CFR Part 807 Subpart E. A 510(k) must demonstrate that the device is substantially equivalent to one legally, commercially distributed in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent.

36. Under the CFR, a 510(k) is required when:

a.) Introducing a device into commercial distribution (marketing) for the first time after May 28, 1976;

b.) A **different intended use** is proposed for a device which is already in commercial distribution. 21 CFR 807 specifically requires a 510k submission for a major change or modification in intended use. **Intended use is indicated by claims made for a device in labeling or advertising. Most, if not all changes in intended use will require a 510(k)**; or

c.) There is a change or modification of a legally marketed device and that change could significantly affect its safety or effectiveness.

21 CFR 807.81. (Emphasis supplied). A few Class II devices are expressly exempt from Premarket Notification, none of which apply here.

37. If the FDA makes a finding of "substantial equivalence" based on the manufacturer's Premarket Notification, the device is then "cleared" for marketing and can be marketed only for the intended use stated on the label as cleared by the FDA.

38. If the manufacturer intends to market the device for a new or different intended use from that cleared for the predicate device, a new 510(k) Notification is required to include supporting information to show that the manufacturer has considered what consequences and effects the new use might have on the device's safety and effectiveness.

39. The manufacturer of a medical device is not permitted to promote its device for any use other than the intended use on the label as cleared or approved by the FDA.

40. A medical device is "misbranded" if the manufacturer of the device has failed to provide the FDA with Premarket Notification of a new or non-FDA-sanctioned intended use ninety days prior to introducing the device into interstate commerce for such use.

41. The FDCA also contains provisions on misbranding and false or misleading labeling. According to Section 502, a device is misbranded if: its labeling is false or misleading in any way; its label does not bear adequate directions for use, including warnings against use in certain pathological conditions; it is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling.

42. A device may be deemed "misbranded" if its label, including *all* written, printed, or graphic matter upon any article or any of its containers or wrappers or any other thing accompanying such article, at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce, fails to reveal material facts, the consequences

that may result from use, or the existence of a difference of opinion about its appropriate use. *See, e.g.* 21 U.S.C. §§ 331(a) and (b), 352(a), (I) and (n); 21 C.F.R. § 201.57. The term "accompanying" a product, as used in Section 502, has been interpreted by the courts to include posters, tags, pamphlets, circulars, booklets, brochures, instruction books, etc. and "most if not all advertising" about the product.

False Claims Act

43. The False Claims Act provides, in pertinent part, that any person who:

> **(A)** knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> **(B)** knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> **(C)** conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
> ...
> **(G)** knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410[1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.

44. For purposes of the False Claims Act, the terms "knowing" and "knowingly" mean that a person, with respect to information; (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud. 31 U.S.C. § 3729(b).

45. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the False Claims Act civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

The Medicare Program

46. Medicare is the Federal health insurance program that was created in 1965 when Title XVII of the Social Security Act was adopted. 42 U.S.C. §§ 1395, *et seq*. Medicare covers people of age 65 and older regardless of their income or medical history. Coverage extends to about 46 million Americans.

47. Medicare is organized into four parts. Part A pays for inpatient hospital stays, skilled nursing facility stays, home health visits (also under Part B), and hospice care. Part B covers physician visits, outpatient services, preventive services, and home health visits. Part C, the Medicare Advantage program, allows beneficiaries to enroll in a private health organization, such as a health maintenance organization (HMO), and receive all Medicare-covered benefits. Part D is the voluntary, subsidized outpatient prescription drug benefit.

48. The Centers for Medicare and Medicaid Services (CMS) administers Medicare. However, most of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as Fiscal Intermediaries. Fiscal Intermediaries accept and pay reimbursement claims under Medicare Part A and some claims under Part B. Acceptance and payment of claims under Medicare Part B are completed through "Medicare Carriers."

49. CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions. 42 C.F.R. §405.201.

50. Medicare may reimburse for Class II devices if they are approved by the FDA pursuant to the Premarket Notification process.

51. Under Medicare regulations, Medicare will not reimburse providers or institutions or medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not "reasonable" and "necessary" under section I 862(a)(l)(A) of the Act or because it is excluded from coverage for other reasons. Medical devices that are not approved for marketing by the FDA are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA. Services that are excluded from coverage include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from related noncovered services.

52. Reimbursement decisions are handled locally by CMS contractors. These contractors make and issue written Local Coverage Determinations, which are published and with which all Medicare providers under their purview must comply. According to CMS, "Local coverage determinations (LCDS) are defined in Section 1869(f)(2)(B) of the Social Security Act (the Act). This section states: "For purposes of this section, the term 'local coverage determination' means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on

an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A)."

The Anti-Kickback Statute

53. The Anti-kickback Statute ("AKS") prohibits any person or entity (including physicians or hospitals) from "knowingly and willfully" soliciting, receiving, offering or paying "any remuneration, indirectly, overtly or covertly, in cash or in kind" in return for "referring an individual to a person for the furnishing of any item to or service for which payment may be made in whole or in part under a federal health care program." 42 U.S.C. §1320a-7b(b)(l) & (2). This includes intent to induce referrals or business orders, including the utilization of medical devices paid as a result of the volume or value of any referrals or business generated. *See* 42 C.F.R. §1001.952(f).

54. The definition of "federal health care program" for purposes of the AKS includes Medicare, Medicaid and Tricare. This provision makes it unlawful for a physician to make a referral that will lead to a claim being submitted to Medicare for services or products supplied by an entity (such as a medical device company) with which the physician has a financial relationship, unless the relationship is not intended to induce referrals and is exempt under a statutory or regulatory safe harbor.

55. The AKS was passed because of Congressional concerns that payoffs, to those who can influence health care decisions, will result in goods and services being provided that are medically unnecessary, or even harmful, to a vulnerable patient population. To protect the integrity of Federal health care programs from these difficult-to-detect harms, Congress enacted a prohibition against the offer or payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality care.

56. The Balanced Budget Act of 1997 amended the Medicare Anti-Kickback Statue to include administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. §1320a-7a(a).

57. Such remunerations are kickbacks when paid to induce or reward physicians' utilization of medical devices. Kickbacks increase Government-funded health benefit program expenses by inducing medically unnecessary overutilization of prescription drugs, medical devices and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices, as a physician may use a medical device based on the physician's own financial interests rather than according to the patient's medical needs or safety.

58. The Medicare Anti-Kickback Statute contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. §1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect Defendant's conduct in this case.

59. The Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), amended the Medicare Anti-Kickback Statute or "Social Security Act," 42 U.S.C. §1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the False Claims Act. PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of the Social Security Act's anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation."

60. At all times relevant herein, compliance with the Anti-Kickback Statute has been a condition to participation for a health care provider under Medicare, Medicaid and other federally and state-funded healthcare programs. Moreover, compliance with the AKS is a condition of payment for claims made to such programs for reimbursement for services

61. The Anti-Kickback Statute not only prohibits outright bribes, but also prohibits any payment or other remuneration by a manufacturer to a physician or other person or entity which has as one of its purposes the inducement of the physician to perform procedures using the manufacturer's products or to induce the physician to influence or recommend use of the manufacturer's product.

62. In addition, "the prohibition applies not only to traditional forms of remuneration, such as cash payments, but also to indirect payments, which could include investment opportunities, especially when terms of the investment are extremely advantageous for a physician, or where the physician-investor has a financial interest in generating business for the company." Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern, at p. 4, (May 2016) available at www.finance.senate.gov, citing HHS OIG, OIG Advisory Op., No. 97-5 (Oct. 6, 1997); HHS OIG, Special Advisory Bulletin: Contractual Joint Ventures, 68 Fed. Reg. 23,148, 23,150 (Apr. 30, 2003).

63. In addition, certain providers, such as hospitals like Sanford, participating in Federal healthcare programs must annually certify compliance with the AKS. For hospitals, this certification is included in the CMS Form 2552 cost report that such providers are required to submit. Medicare and its designees rely on this certification and the representations made therein in making payments to providers. The "advisory" language preceding the certification section reads as follows:

> MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CNIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, **IF SERVICES IDENTIFIED BY THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECILY OR INDIRECILY OF A KICKBACK OR WERE OTHERWISE ADMINISTRATIVE ACTION, FINES, RESULT**.

(Capitals in original; bold emphasis added). The specific certification language then reads:

> CERTIFICATION BY OFFICER OR ADMINISTRATOR OR PROVIDER(S)
> I HEREBY CERTIFY that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by [Provider Name(s) and Number(s)] for the cost reporting period beginning [date] and ending [date] and that to the best of my knowledge and belief it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted **I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.**

(Capitals in original; bold emphases added)

64. Payment to providers under Federal healthcare programs - not just participation in those programs - is conditioned upon this express certification that the provider has complied with the AKS. Providers' suppliers are also bound by the rules and regulations underlying the AKS. *See* § 1001.952(h)(2).

65. The "safe harbor" provisions of the AKS apply to certain narrow forms of payment *(see* 42 U.S.C § 1320a-7b(b)(3)(A) and (b)(3)(E); 42 C.F.R. § 1001.952(h)), but Relators do not bear the burden of alleging or proving inapplicability of the safe harbor as an element of the claims pleaded here. Regardless, none of the safe harbor provisions apply to any of the payments or conduct alleged herein.

The Stark Law

66. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § l395nn *et seq.*, known as the "Stark law" after Congressman Pete Stark, prohibits a physician from making a referral that will lead to a claim being submitted for "designated health services," the definition of which encompasses services rendered using equipment manufactured by Medical Designs, where the referring physician has a nonexempt "financial relationship" with the manufacturer. 42 U.S.C. § 1395nn(a)(l), (h)(6). The Stark law provides that the manufacturer shall not cause to be presented a Medicare or Medicaid claim for such services.

67. The Stark law also prohibits payment of claims rendered in violation of its provisions. 42 U.S.C. §1395m(a)(l),(g)(1).

Physician Owned Distributorships (PODs)

68. There has been increased scrutiny in the last few years of Physician Owned Distributorships ("PODs"). The Senate Finance Committee and the Department of Health and Human Services (HHS OIG) have both issued reports and alerts warning of the inherent conflicts presented by these structures.

69. In 2013, the OIG issued a Special Alert in which it called them "inherently suspect under the anti-kickback statute." Department of Health and Human Services Office of Inspector General: Special Fraud Alert: Physician-Owned Entities (March 2013) available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf

70. The OIG explained that PODs like the one at issue here "raise four major concerns typically associated with kickbacks" as follows:

> … corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition. This is because the financial incentives PODs offer to their physician-owners may induce the physicians both to

> perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices.

Special Fraud Alert at 2.

71. The spinal devices at issue here – the Bullet Cages and Samba Screws – are known as physician preference devices since there are other comparable devices on the market that are similarly indicated and can perform just as well or better than these devices.

72. PODs dealing in physician preference devices are highly suspect as they are rife for overutilization. The OIG noted:

> We are particularly concerned about the presence of such financial incentives in the implantable medical device context because such devices typically are "physician preference items," meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed

Id.

73. Dr. Asfora is the sole owner of Medical Designs and the only physician currently routinely using the Bullet Cages. He also substantially changed his utilization of the Bullet Cages greatly after FDA approval. These facts demonstrate the intent of Defendants to use Dr. Asfora's position as a surgeon to overutilize Medical Designs' devices.

74. The OIG discussed this very situation:

> The anti-kickback statute is not a prohibition on the generation of profits; however, PODs that generate disproportionately high rates of return for physician-owners may trigger heightened scrutiny. … Our concerns are magnified in cases when the physician-owners: (1) are few in number, such that the volume or value of a particular physician-owner's recommendations or referrals closely correlates to that physician-owner's return on investment, or (2) alter their medical practice after or shortly before investing in the POD (for example, by performing more surgeries, or more extensive surgeries, or by switching to using their PODs' devices on an exclusive, or nearly exclusive basis).

Special Fraud Alert at 4.

75. It also warned as is highly relevant here, "the risk of fraud and abuse is particularly high in circumstances when such physicians-owners are the sole (or nearly the sole) users of the devices sold or manufactured by their PODs." *Id.*

76. In its most recent report, the Senate Finance Committee also focused on PODs, echoing many of the concerns raised by the OIG and describing the issue as follows:

> Surgeons have a unique and powerful role in influencing both patient and medical practice decisions. When a surgeon recommends surgery, patients are strongly inclined to follow their doctor's recommendation. Within the field of spinal surgery, spinal fusions are among the most serious and costly types of back surgery, and are typically only recommended for patients with the most serious back problems. Spinal implants are generally "physician preference," meaning hospitals typically purchase the devices recommended by their surgeons. **Spinal surgeons therefore have significant influence over both the frequency of spinal fusion surgeries and the devices used in those surgeries.**
>
> **Unchecked, this position of power can give POD spinal surgeons the opportunity to grant themselves a steady stream of income by increasing the use of the products supplied by their POD. PODs present an inherent conflict of interest that can put the physician's medical judgment at odds with the patient's best interests.**

Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern, at p. 1, (May 2016) available at www.finance.senate.gov. (Emphasis added).

77. With the available research and reports, the Senate Finance Committee enumerated six major concerns with PODs, at least four of which are directly implicated with Dr. Asfora and Medical Designs herein:

1. "As stated by the HHS OIG in the 2013 SFA, financial transactions involving PODs may violate the Anti-Kickback Statute, Stark Law, or both."

2. "POD physicians face an **inherent conflict of interest** when they have a financial incentive to perform surgeries. This incentive may compromise a doctor's medical judgment and place financial incentives at odds with the best interest of the patient."

> 3. **Overutilization may occur** if physicians perform additional, more complex, or medically unnecessary surgeries to garner POD financial incentives. Analysis by the Committee and HHS OIG suggest that POD doctors are, in fact, overutilizing spinal implant products." and
>
> 4. As a result of potential conflicts of interest and overutilization, **PODs compromise patient safety as patients receive high-risk treatment beyond what is medically warranted**. Any unnecessary medical procedure increases the risk that the patient may be harmed. … Our concerns about medically unnecessary services are especially acute in the case of seniors who, due to their age, are less physically capable of withstanding the rigors of complex, invasive spine surgery."

Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern, at pp. 2-3, (May 2016) available at www.finance.senate.gov. (Emphasis added).

78. As is detailed below, the Government's concerns materialize with Dr. Asfora. Dr. Asfora has an inherent conflict of interest as the sole owner of Medical Designs and as the only spine surgeon in America that uses its (his) medical devices.

79. Further, Dr. Asfora has a personal, financial incentive not only to use Medical Designs devices on his patients, but to use more than are needed and when not medically necessary. As a result, the unsuspecting patients, often vulnerable and elderly in Dr. Asfora's case, are put at unnecessary risk of complication, unnecessary surgical procedures and are indeed harmed.

Sanford Health and Sanford Clinic Overview

80. Sanford Clinic is a multi-specialty, outpatient clinic located inside Sanford Medical Center in Sioux Falls, SD that directly employs Dr. Asfora and the Relators.

81. Sanford Neurosurgery and Spine is part of Sanford Clinic along with Sanford Orthopedics and Sports Medicine. Sanford Clinic currently employs 3 neurosurgeons and 1 part-time locums physician.

82. Approximately 38% of Sanford Clinic's yearly patients are Medicare beneficiaries, while the other largest segment are beneficiaries of state-based insurance.

Medical Designs and Dr. Asfora Overview

Previous FCA lawsuit and settlement

83. Dr. Asfora is a physician specializing in neurosurgery. Dr. Asfora joined Sanford Health in 2007. Prior to 2007, he was an independent neurosurgeon who worked at both Sanford Medical Center and Avera Health. He joined Sanford Clinic after separating from Avera Health in 2006.

84. Defendants Dr. Asfora and Sanford are repeat FCA offenders.

85. Dr. Asfora and Sanford Health have been sued under the False Claims Act before. In 2013, Sanford Health settled a *qui tam* brought by then Sanford Clinic employee David DuBay. The limited Compliant alleged that Dr. Asfora was engaged in a kickback scheme to pay other surgeons for using the Bullet Cage his company, Medical Designs, manufactured and sold.

86. Sanford settled for $625,000 before litigation and with all defendants denying liability.

87. The covered conduct of that settlement only covered kickbacks disguised as consulting fees to physicians to induce their use of the Bullet Cage from May 2010 through April 2011 and in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

88. The covered conduct did not include claims after April 2011, claims involving medical necessity, upcoding or off-label, and claims involving other Medical Designs devices like the Samba Screw. The allegations herein are not subsumed by the previous lawsuit or the

covered conduct of its limited settlement. This Complaint brings claims and alleges facts different in time, scope and nature from those in the previous complaint.

89. Medical Designs and Dr. Asfora have not ceased or even curbed any of their fraudulent activities since the settlement. Instead, they have expanded their fraudulent conduct greatly and become more brazen, now risking patient injury on a routine basis for their own financial gain.

90. Sanford has also not acted in such a way so as to stop, curb, properly supervise or discipline the Asfora fraud, which has been reported to it by multiple other surgeons, including the Relators. Instead, Sanford has ultimately purposefully chosen to encourage the fraud and benefit from it.

The Bullet Cage

91. Dr. Asfora is the creator of the Asfora Bullet Cage, manufactured by Medical Designs, LLC, of which Dr. Asfora is the 100% owner.

92. Medical Designs is and has always been a physician owned distributorship ("POD").

93. According to its 510(k) #090048, the Bullet Cage is a Class II device intended to be used in posterior lumbar interbody fusion. **It is only indicated for use in "one or two levels,"** in the lumbar spine (from L2 to S1), and is intended to be used in "skeletally mature patients with degenerative disc disease (DDD)," which "may also have up to Grade I spondylolisthesis" (the lowest grade).

94. Additionally, the original 510(k) and the 2012 supplement (#K112648) both indicate that six months of conservative treatment is indicated before use of the Bullet Cage.

"Patients should be skeletally mature and have had at **least six (6) months of non-operative treatment prior to implant.**" (#K112648). (Emphasis added).

95. Critically, Dr. Asfora never told the FDA, but intentionally omitted from all filings, that the Bullet Cage was intended to be used in more than two levels or in the vertebral body. The FDA was not aware of these facts and did not issue approval of these as indications. After initial approval, Dr. Asfora also never applied for a new 510(k) citing these new uses and requesting these indications.

96. Approved by the FDA in 2009, upon information and belief, the Bullet Cage is currently only used by Dr. Asfora.

97. Critically, no other physicians at Sanford or outside Sanford have routinely used the cage for the last few years, particularly as technology has advanced, which, in large part, has rendered the Bullet Cage obsolete.

98. Currently, Dr. Asfora's POD (Medical Designs) sells the cages, Dr. Asfora orders them for his patients and Sanford Health purchases them at a price of between $2,500-$5,000 per cage. Medicare, Medicaid and South Dakota insurance then reimburse for the device.

99. There is a clear financial incentive for Dr. Asfora to use his own device on his patients over those of his competitors, even as other physicians choose not to use this now outdated technology.

100. There is also a clear financial incentive for Dr. Asfora to use as much of his device as possible, since he personally stands to gain financially from the sale of *each* Bullet Cage and Samba Screw. As such, he makes much more money, personally, by not only using

his device over those of a competitor, but also if he implants four cages, for example, than if he only implants one.

101. Creating a dangerous conflict that risks real patient harm, the more Medical Designs' devices he implants, the more money flows directly back to him personally.

102. Recognizing this conflict, any independent review of his records leads to the inevitable result that his decision to almost always fuse every patient he sees and to always use his Medical Designs manufactured devices, are decisions based not on the patients' medical needs and best interest, but only based on his own financial incentive and that of Sanford.

The Samba Screw System

103. Manufactured by Medical Designs also, Dr. Asfora also developed, uses and sells a device called the Samba Screw.

104. The Samba Screw is a metallic bone screw that is designed to stabilize the sacroiliac (SI) joint. It was approved in August 2012 under 510(k) #K121148.

105. Per its 510(k), the Samba Screw is a Class II device classified as "smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)."

106. Its intended use is "for fixation of sacroiliac joint disruptions" and "this fixation device is only to be used in skeletally mature patients." Of note, it is not indicated for generic SI joint pain.

107. In 2014, Dr. Asfora approached Dr. Wellman and Dr. Troy Gust (another Sanford neurosurgeon) and told them that he would soon be selling pedicle screws. He told them that they could buy into the arrangement and he offered them $500 "under the table" for each of his pedicle screws they use. This is an offered kickback. Both doctors strongly declined and reported this incident to multiple Sanford administrators, who took no action.

108. Shortly thereafter, Dr. Asfora began a relationship with Orthofix, Inc. representative Jesse Talcott.

109. According to its website,[1] Orthofix, Inc. secured an exclusive licensing and distribution agreement for Dr. Asfora's Samba-Screw® SI Fixation System in around 2014.

110. However, upon information and belief, Dr. Asfora still owns the device. Dr. Asfora sells his Samba Screws to Orthofix at a profit. Then, whenever he can use a fixation device on his own patients, either on or off-label, Dr. Asfora uses the Samba Screw exclusively for fixation. Asfora places an order through Sanford Health using Orthofix sales representative Jesse Talcott (who also is believed to be on Medical Designs payroll or otherwise receives compensation or benefit from this relationship with Dr. Asfora).

111. As such, though using the façade of a middle-man, Medical Designs is still a POD selling the Samba Screw, which is used exclusively by Dr. Asfora on his patients and from which he personally profits.

112. Like with the Bullet Cage, Dr. Asfora is deeply conflicted by this arrangement as he personally benefits from the use and overuse of the Samba Screw on his patients.

113. Dr. Asfora uses the Samba Screw in his surgeries to the exclusion of equivalent competitor devices and he does not advise his clients of his inherent conflict. He also uses the screws when not medically indicated and for uses for which they are not indicated by the FDA, all without advising his patients and, eventually, to their detriment.

114. Given this relationship, the inherent kickbacks in it and the over-utilization of the device for medically unnecessary procedures, all procedures using the Samba Screw by Dr. Asfora are tainted and non-reimbursable.

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[1] *See* http://web.orthofix.com/AboutUs/Pages/Company-History.aspx

Specific Allegations

An Environment Fertile for Fraud

115. Sanford created and encourages an environment and a culture fertile for fraud.

116. The covered conduct from the previous *qui tam* was limited in time through April 2011.

117. Sanford has taken numerous overt steps encouraging fraud, all to maximize its reimbursement.

118. In the end of the year 2011, Sanford Health switched its physician compensation system for all physicians. Previously, essentially, physicians were paid the production income after expenses attributable to them. As of the end of 2011, the physicians began to be compensated based on RVUs (Relative Value Units), creating a personal and financial incentive for physicians to maximize reimbursement.

119. Sanford also began aggressively pushing its surgeons to bill for their PAs in surgery regardless of whether or not they were present and actively assisted.

120. Under the CMS regulations of PAs, "Assistant at surgery services are those services rendered by physicians or nonphysician practitioners who actively assist the physician in charge of performing a surgical procedure." MLN Matters Number: MM6123, "Payment of Assistant at Surgery Services in a Method II Critical Access Hospital (CAH)" (release date October 24, 2008) at p.2.

121. "Medicare law at section 1833(a)(1)(O) of the Social Security Act authorizes payment for services that a PA furnishes as an assistant-at-surgery. Specifically, when a PA actively assists a physician in performing a surgical procedure and furnishes more than just ancillary services, the PA's services are eligible for payment as assistant-at-surgery services."

Medicare Claims Processing Manual, Chapter 12 - Physicians/Nonphysician Practitioners (Rev. 03-11-16), at Sec. 110.2.

122. The American College of Surgeons has issued policy statements and national studies in which it stated that PAs are not to operate alone:

> "ideally the first assistant at the operating table should be a qualified surgeon or a resident… it may be necessary to utilize nonphysicians as first assistants. Surgeon's Assistants (SAs) or physician's assistants (PAs) with additional surgical training should meet national standards and be credentialed by the appropriate local authority. **These individuals are not authorized to operate independently.**"

American College of Surgeons, "Physicians as Assistants at Surgery: 2013 Study," at II.(G), available at https://www.facs.org/~/media/files/advocacy/pubs/pas%202013.ashx (last accessed 8/10/16). (Emphasis added).

123. In addition, even if the Dr. Asfora's PAs were properly "actively assisting" in surgery by performing wound closure while Dr. Asfora was scrubbing out and no longer present, and even if they were authorized to perform these tasks in the surgeon's absence, these tasks are still not reimbursable by Medicare as they have been expressly excluded.

124. Medicare publishes a list of CPT procedure codes each year for which Medicare will not reimburse a first assistant at surgery. According to Medicare, the "list consists of procedures that Medicare has determined required an assistant-at-surgery in fewer than 5% of the cases nationally. The list applies to all first assistants, PAs, MDs and NPs." Included in this list of non-reimbursable CPT codes are the codes for wound closure, including: 12031, 12032, 12034, 12035, 12036, 13100, 13101 and 13160, which, if coded correctly, would be most typically used for closure after Dr. Asfora's surgeries.

125. Despite all of these polices, regulations and standards, Sanford administration began to pressure the Sanford Clinic neurosurgeons to have Physician's Assistants ("PAs") close surgeries and bill for their surgical assistance. This pressure from Sanford management continued for years. At almost every meeting, the managers told the neurosurgeons, including Relator Dr. Wellman, to bill for PAs to close surgeries. Dr. Gust and Dr. Wellman continually refused, responding to Sanford administration that it is illegal to bill for a PA unless they were present during the surgery and were a meaningful part of the surgery and actively assisted.

126. At the same time, Relator Dr. Wellman became aware that Dr. Asfora was not similarly refusing the request, but was indeed billing for his PA when the PA was either not there in the surgery at all, or when the PA only came in at the very end for closing and at the time Dr. Asfora is leaving the OR, thus not actively assisting. Relator Dr. Wellman and others repeatedly raised this concern with administration, to no avail.

127. Later, in or around March 2015, Sanford administration (Joe Adams, Neurosurgery Clinic Manager) informed the physicians that 5% would be withheld from their compensation based on "quality measures." The neurosurgeons were verbally told that they must begin billing for a PA in each surgery and that 5% of their compensation would be withheld unless the surgeons billed for a PA whether or not the PA was actually present in the surgery.

128. Given the unusualness and impropriety of this new policy, Relator Dr. Wellman and other physicians told Joe Adams that the request and the new PA policy must be put into writing. They also reiterated their understanding that it is fraudulent for a surgeon to bill for a PA unless the PA has meaningful participation and actively assists in the surgery. They also felt it was an unusual demand as it was unnecessary to the practice, did not enhance patient

care and appeared to be a purely billing issue. The request was never made in writing and the 5% was not withheld as threatened. However, Dr. Asfora continued throughout this time to bill for his PAs including when they were never present or were only present for wound closure but did not actively assist in the surgery.

129. Throughout 2011 and 2012, the medical peer review committee specifically investigated Dr. Asfora's cases. Relator Dr. Wellman was one of the long-standing members of the peer review committee.

130. Because there were so many physician complaints, nursing complaints, and other complaints to Sanford management about Dr. Asfora being too aggressive in his surgeries, performing medically unnecessary procedures or levels and performing too many levels on spinal fusion surgeries, the peer review committee asked Relator Dr. Wellman and his colleague, Dr. Geoff Haft, to specifically review some of Dr. Asfora's cases.

131. There had been a recognizable and dramatic change in Dr. Asfora's practice since he could use his Bullet Cage. Drs. Wellman and Haft reviewed the cases and determined that Dr. Asfora was not correctly performing surgeries as he was performing medically unnecessary procedures and unnecessary multi-level procedures.

132. The other members of the peer review (approximately 15 members) wanted to send the Dr. Asfora cases out for external peer review after collecting cases for six months. The then Chief Medical Officer, Dr. Aspaas, took charge of collecting the cases and informed the committee that he would send them out for outside peer review. At many meetings when asked for updates, Dr. Aspaas kept saying the cases had been sent out but the process was simply taking a long time. He said at one point that, "it would take time and we're doing the right thing." No results were ever shown to the committee.

133. Relator Dr. Wellman and others (including Dr. Haft and another Sanford neurosurgeon, Dr. Troy Gust) continued to complain, note and express concern about the spine fusion cases they were seeing from Dr. Asfora because the physicians share patients through call and see each other's patients after surgery. The continued to note to management Dr. Asfora's medically unnecessary procedures and levels.

134. Around the same time, Relator Dr. Bechtold spoke with Dr. Aspaas and repeatedly requested an outside review of Dr. Asfora's sacroiliac ("SI") fusion cases.

135. Dr. Bechtold communicated his grave concerns to Dr. Aspaas that Dr. Asfora should not be doing such a large number of SI fusion surgeries and that he was performing medically unnecessary surgeries by operating on people with no indication for sacroiliac spine surgery and/or lumbar surgery. Dr. Bechtold relayed to Dr. Aspaas that he had formed this opinion after seeing many of Dr. Asfora's patients who come to him with continuing pain after undergoing unnecessary Dr. Asfora spine surgery.

136. Dr. Bechtold raised concerns that in his assessment the hip was the issue all along with many of these patients and the spinal surgery was never indicated or medically necessary. Alternatively, patients often report that they are being sent for evaluation of their hip because Dr. Asfora declared to them that their surgeries are "perfect, so it must be your hip" when in reality the spine and SI surgeries clinically appear to be the source of ongoing pain. Dr. Bechtold also advised that the SI fusion is not the right course of treatment until failure of exhaustive non-surgical treatment in the presence of significant, limiting pain and that, particularly on an elderly patient as are at issue with Dr. Asfora, a more conservative, less risky, non-surgical treatment is done by almost all surgeons and is the standard, whereas Dr.

Asfora performs surgery on nearly every patient with SI joint pain, and implants his own devices for a profit.

137. After a long time and unrelenting complaints from Dr. Bechtold and, as reported by administration, similar simultaneous complaints from a physician providing chronic pain management for many of Dr. Asfora's patients, Dr. Hansen, Sanford finally sent out a series of cases for outside review. However, this review appeared to be merely a description of procedures rather than a judgment of medical necessity or proper implementation. Dr. Bechtold was given access to the review in a confidential setting, and the comments were very memorable. These include a number of comments about the unusual use of hardware in a way not seen by the specialist and many descriptions of hardware positioned in a less than ideal manner. No findings or recommendations were made despite an unreasonably lengthy review with no apparent investigation of the clinical background of the individual cases.

138. It started to become clear to Dr. Bechtold at this point that Sanford was not interested in meaningful review and supervision of these medically unnecessary cases.

139. In 2012, the last of the Sanford physicians stopped routinely using the Bullet Cage as it was felt to be outdated with new technologies, including an expandable cage. Dr. Asfora is the only surgeon to routinely continue its use.

140. In or around 2013, Dr. Michael Wilde became Chief Medical Officer. When he took over, Dr. Wilde met with Drs. Wellman, Haft and Gust separately from their colleague, Dr. Asfora. Dr. Wilde told each of them that he had all these Dr. Asfora cases that Dr. Aspaas had collected on unnecessary, multi-level spinal fusion cases. He informed them that the cases had never been sent out for peer review and could not be sent out now without a formal complaint.

141. On or about October 24, 2014. Dr. Wellman was on call and reviewed the images of a Dr. Asfora patient, [redacted] Dr. Wellman noted that Dr. Asfora had performed surgery on the wrong spinal level, human error that could happen even to the most careful surgeon. However, Sanford's and Dr. Asfora's responses were alarming.

142. Dr. Wellman called Dr. Asfora, who agreed and admitted that the wrong level had been done. After the call and verbal admission of the mistake, Dr. Wellman was told by Dr. Asfora that he would notify his patient of the error the next work day.

143. When Dr. Wellman checked the operative note, which was oddly and against protocol dictated at least a week later, Dr. Asfora had not, in fact, documented the wrong level.

144. Sanford covered for Dr. Asfora.

145. Dr. Wellman spoke with Alison Sably in Risk Management about the case. She reported back to Dr. Wellman that she had "done an investigation" and found nothing to be done incorrectly. The extent of her investigation is unknown but Dr. Wellman was not consulted during the investigation and the patient was never notified of the clear error.

146. On or about April 14, 2015, Dr. Haft brought the patient [redacted] wrongful level surgery case to the peer review committee.

147. On or about April 16, 2015, Dr. Wellman wrote a letter to Dr. Wilde, the Medical Director, withdrawing from the peer review committee review of the Dr. Asfora patient [redacted] since he had been already involved in its review.

148. A few months after the [redacted] wrong level case, Dr. Wellman discovered another wrong-level case performed by Dr. Asfora. Dr. Wellman saw the patient x-ray for patient [redacted] while he was about to review x-rays for his own patient. In [redacted]'s case, Dr. Asfora had not seen the patient pre-operatively. Dr. Asfora did the incorrect spinal level on the patient and

then also did the correct level after he realized his mistake. Dr. Asfora spoke with Dr. Wellman afterwards and blamed the nursing staff for the error.

149. Sanford covered for Dr. Asfora again. Someone complained about this incident to Dr. Haft, who reported this wrong level to peer review as well. Again, no discipline ultimately followed although both wrong level cases were confirmed by outside review.

150. On or about July 9, 2015, Dr. Wellman met with Joe Adams, his clinical supervisor. Dr. Wellman relayed that he was concerned that Dr. Asfora was conflicted and personally profiting from implanting plates and screws through his POD and that last year Dr. Asfora had asked Relator and Dr. Gust to join his POD and to pay them for using his screw. Though they strongly declined, the offer was alarming in itself.

151. Dr. Wellman also reported to Joe Adams that the process by which Dr. Asfora gets his plates and screws has changed in that his sales representative, Jesse, now sells to Sanford and Dr. Asfora still gets a cut (outside of Medical Designs) through some sort of loose or shadow POD. Dr. Wellman expressed his opinion to Joe Adams that this process was possibly illegal and against Sanford policy.

152. Joe Adams stated that he would discuss these concerns and allegations with his superiors and would follow up.

153. On or about July 14, 2015, in a meeting with Joe Adams, Andy Munce and COO of Clinic Brad Schipper, Drs. Wellman and Gust discussed Dr. Asfora again. During the discussion, both doctors raised concerns that Dr. Asfora is getting paid for implants and is conflicted. The doctors said that, particularly in light of the earlier OIG investigation and settlement, these Dr. Asfora issues need to be addressed and corrected immediately. Administrative representatives said they would address these concerns and report back.

154. On or about August 5, 2015, Drs. Wellman and Gust met with Compliance Officer, Lois Marshall, at the request of doctors who wanted a follow up on their reported concerns regarding Dr. Asfora, including his new shadow POD relationship with sales representative Jesse Talcott. The doctors again reported that Dr. Asfora is conflicted and is personally profiting from implants sold by Jesse to Sanford. The reported concerns at this meeting included: that Dr. Asfora devices get sold through Jesse as a middleman; that the pattern of Dr. Asfora's surgeries has changed, with a sharp increase in aggressive, medically unnecessary surgeries and unnecessary multiple levels; and how Dr. Asfora had approached the doctors with an offer to pay them kickbacks for use of his pedicle screws after Sanford and Asfora had settled a similar kickback lawsuit less than just two years before.

155. Lois Marshall promised to review the Asfora/Jesse relationship. Ms. Marshall left the meeting stating she would look into the Jesse link and also stated that she would fire Dr. Asfora if she could.

156. On or about August 17, 2015, in the Sanford surgeon's lounge, Dr. Asfora approached Dr. Wellman. Dr. Asfora stated that he met with administration the previous week. He also explained his kickback scheme as follows: (a) Medical Designs bought bulk pedicle screws and is the sole distributor of those screws; (b) Dr. Asfora then sold the screws to Jesse Talcott; and (c) Jesse Talcott works for both Orthofix (which bought his Samba Screw) and for Medical Designs who sells them to Sanford when Dr. Asfora uses them in surgery.

157. On or about September 23, 2015, Drs. Wellman and Gust met with Compliance Officer, Lois Marshall and Andy Munce. Ms. Marshall stated that her investigation revealed Dr. Asfora bought bulk screws and sold them to Jesse and that Jesse now sells them. Lois reported that they did not find anything wrong with the arrangement as Dr. Asfora stated he did

not profit from it. BW and TG asked if she had done any investigation beyond simply speaking to Dr. Asfora. She admitted that she did not. The doctors expressed concerns that Dr. Asfora's denial made no sense because if he was not profiting he would not have asked the doctors to join his arrangement and he would pay them to do so. The doctors also reported that they knew Dr. Asfora was routinely billing for his PA in surgery when they were not present in the OR and that Rick Schaefer, a MD rep, had admitted that he was told to document PA assist in the OR report when they were not there. Lois Marshall dismissed their concerns and the doctors expressed frustration and disagreement with this conclusion.

158. On or about September 24, 2015, Drs. Wellman, Gust and Haft met with Dr. Wilde to again discuss Dr. Asfora and Dr. Wilde's plans to correct the numerous issues. The doctors provided a laundry list of concerns regarding Dr. Asfora, including but not limited to, medically unnecessary surgeries, off-label and medically non-indicated surgeries, deep conflict making and personally benefitting from his Bullet Cage and Samba Screws, cover ups of wrong site surgeries and fabricating the medical records, and fraudulent billing for his PAs in surgery.

159. Dr. Wilde stated at this meeting that he thought Dr. Asfora would get fired. However, he also discussed how difficult it might be to terminate him. First, he warned that CEO "Kelby hates firing doctors – hates it," so the CEO was an initial obstacle according to Dr. Wilde. Second, Dr. Wilde stated to the group, "from what I've heard from Farritor and Ken Aspaas, is that Asfora was right in the crosshairs, they were going to pull the trigger [to fire him], and Kelby said no," Dr. Wilde in this meeting called this a "**get out of jail free card**" for Dr. Asfora. Dr. Wilde stated at this meeting that he was trying to get Dr. Asfora terminated or to leave, but noted how difficult it would be to achieve.

160. At yet another meeting on or about October 6, 2015, Drs. Wellman, Haft and Gust met with Paul Hanson (Executive Vice President Sanford, Sioux Falls) and Brad Schipper (Chief Operating Officer Sanford, Sioux Falls). They again raised concerns regarding Dr. Asfora, including the Jesse Talcott relationship and the PA billing issues. There was no response from administration at this meeting.

161. On or about October 13, 2015, Drs. Gust and Wellman were called into a meeting late in the afternoon. On the way to this meeting, Dr. Wellman and Dr. Gust ran into Dr. Asfora in the hallway. Dr. Asfora stated that he had just been fired and that he was very upset. He also stated that he had "dirt and skeletons" on Sanford and he would be hired back or else he would use what he had against Sanford. He also asked Drs. Wellman and Gust to leave Sanford with him. They declined.

162. Immediately after this run-in with Dr. Asfora, Drs. Wellman, Gust and Haft and Dr. Bhardwaj (pediatric neurosurgeon) met with Dan Blue (Executive Vice President of Sanford Clinic), Dr. Farritor, and Brad Schipper. Dan Blue told the assembled group that Dr. Asfora was fired with a 3-month transition plan to private practice, if he chose to stay in town. Patient transfer issues were discussed. It was stated that Dr. Asfora would be allowed to keep hospital privileges, but that the two open peer review investigations regarding his medical staff privileges might result in the termination of those privileges. Dr. Wellman expressed concern that Dr. Asfora would not actually be asked to leave but would be reinstated. Dr. Wellman was told by Dr. Blue that this would not happen. The administration present at this meeting seemed to be happy with the firing as long overdue.

163. On or about October 20, 2015, Drs. Wellman and Gust met at noon with Brad Schipper, Andy Munce, and Joe Adams. Dr. Asfora's transition plan for call and practice was

again discussed. Dr. Wellman again stressed that Dr. Asfora has significant financial incentive to stay at Sanford because Dr. Asfora has stated that he makes $3.5 million a year off his various implants. Dr. Wellman was again reassured that Dr. Asfora would not be retained. Brad Schipper made a point of stating that he was doing the right thing despite Dr. Asfora's vast financial contribution to Sanford. He promised his personal commitment to seeing this through to completion.

164. Less than one week after this guarantee, on or about October 26, 2015, Dr. Wellman received call from Dr. Asfora stating that he was being reinstated. Dr. Asfora claimed that he had personally spoken to Kelby Krabbenoff (CEO) and to massive and very influential Sanford donor, Denny Sanford, and that they helped him get reinstated.

165. On or about October 28, 2015, Dr. Wellman spoke on the phone with Andy Munce. Andy Munce confirmed for Dr. Wellman that Dr. Asfora had indeed been reinstated. Dr. Wellman expressed shock and displeasure. Dr. Wellman stated to Munce that he was not comfortable with Dr. Asfora as his partner based upon his fraud and the risk to their patients. Dr. Wellman repeated this to Joe Adams in a separate conversation.

166. Dr. Bechtold was in the surgical lounge immediately after Dr. Asfora's reinstatement. He was told by Dr. Asfora that he cannot be fired because Kelby, Nate White (Chief Operating Officer Sanford Health) and Matt Hocks (Vice President Sanford Clinic) know what a great surgeon he is and how much he contributes to Sanford. He declared that the other administrators involved in his firing don't know what they are talking about. Dr. Bechtold interpreted this as a statement from Dr. Asfora that he is untouchable.

167. On or about October 29, 2015, Dr. Wellman met with Dr. Farritor, Lois Marshall, Andy Munce and Dr. Haft. At some point during this meeting, Ms. Marshall from

Compliance discussed that she had not found any concerns regarding the POD issue raised by Drs. Gust, Wellman and Haft separately. Dr. Wellman questioned the methodology of the investigation which only involved speaking with Jesse Talcott and Dr. Asfora and no other witnesses and which reviewed no documents.

168. In this meeting, Drs. Haft and Wellman also reiterated their belief that Dr. Asfora's ownership of Medical Designs had created a serious conflict and that conflict was influencing him to perform unnecessary, multi-level cases and unusual off label use of the Bullet Cage all so he could personally, financially benefit.

169. Also in this meeting, Drs. Wellman and Haft expressly asked Sanford to stop purchasing implants from Medical Designs to prevent this overutilization, the kickbacks, the unnecessary surgeries and the off label use. Dr. Farritor then disclosed that upper management had decided to reinstate Dr. Asfora with a new contract that ties him to maintaining his hospital privileges. Dr. Farritor said "one more mistake" and he will be fired. Drs. Haft and Wellman expressed disagreement and strongly advocated for reconsideration of this decision. The meeting ended without resolution.

170. Drs. Gust and Wellman submitted a letter dated November 4, 2015, filing a formal complaint against Dr. Asfora. This letter was sent to Dr. Dan Blue, Dr. Mike Wilde, Mike Farritor and Paul Hansen.

171. After submission of the formal complaint against Dr. Asfora, Drs. Gust, Wellman and Haft were informed by Dr. Wilde that they could no longer participate in the peer review process due to their conflict with Dr. Asfora. Instead, they are told to bring all cases for peer review to him and he would get outside counsel if needed.

172. Also in November 2015, Dr. Wellman called Dr. Quiton Durword (of the Center for Neurosurgery and Orthopedics, or CNOS) for some general advice on these issues. Dr. Durword encouraged Dr. Wellman to continue his course of action reporting these acts. In that call, Dr. Durword told Dr. Wellman that he had been approached by Dr. Asfora, who personally offered him $2,000 per cage as a kickback for Dr. Durword to use the Bullet Cage in his patients. Dr. Durword reported to Dr. Wellman that he was upset by the offer, that he strongly rejected the offer, and that Dr. Durword told Dr. Asfora not to ever approach him again.

173. On or about November 6, 2015, Drs. Wellman, Gust and Haft met with Dr. Brian Aamlid, Dr. Farritor, Paul Hanson, Brad Schipper and Andy Munce. Dr. Haft led the discussion of the doctors' concerns with Dr. Asfora, including: his over usage and misusage of the medical devices he owns and manufacturers, the unnecessary surgeries and the off label and improper use of the pedicle screws.

174. Administration did not respond. It continued to employ, protect and benefit from Dr. Asfora's fraud.

175. On or about November 9, 2015, Dr. Haft sent a letter to Dr. Dan Blue, Dr. Mike Wilde, Dr. Farritor and Paul Hansen filing a formal complaint against Dr. Asfora.

176. On or about November 18, 2015, Sanford sent response letters to Drs. Gust and Wellman and separately to Dr. Haft. In that letter, Sanford formally recognized Dr. Gust's and Dr. Wellman's complaint letters and stated that, "Sanford's compliance department has investigated the information you provided and the results and/or status of such investigation were recently communicated to you."

177. On or about December 18, 2015, Dr. Wellman telephoned Dr. Wilde regarding a specific patient ([redacted] date of surgery [redacted]/15) where the surgery was medically unnecessary and improper. Dr. Asfora had performed a PLIF in the thoracic spine, which is medically unnecessary, not indicated and very dangerous. The patient developed paralysis. There was no medical reason or necessity whatsoever to perform this procedure other than to insert a Bullet Cage. The patient did not need a cage nor this highly dangerous procedure.

178. Dr. Wellman asked Dr. Wilde to have patient [redacted]'s case independently reviewed. It was not. Dr. Wilde went to Dr. Asfora and told him that Dr. Wellman had complained to Dr. Wilde about Dr. Asfora's thoracic PLIF. Dr. Asfora then confronted Dr. Wellman about the complaint and appeared angry at Dr. Wellman.

179. During the confrontation, Dr. Asfora relayed to Dr. Wellman that he had been told by Dr. Wilde that it's "all ok." Sanford continued to employ, protect and benefit from Dr. Asfora's fraud.

180. On or about February 9, 2016, Dr. Wellman had a discussion with Mike Boose, a representative out of Dakota Dunes. Mr. Boose reported in this conversation that Dr. Asfora had recently interacted with a neurosurgeon at Dakota Dunes who had tried the Samba Screw, which Dr. Asfora had sold to Orthofix. Dr. Asfora asked the neurosurgeon to purchase the Samba Screw directly through him and not through Orthofix, solidifying Dr. Wellman's understanding that Dr. Asfora did continue to personally financially benefit from and control the sale of the Samba Screw.

181. On or about February 25, 2016, Drs. Gust, Haft and Wellman continued to review complications from Dr. Asfora surgeries in their practices and bring them to Dr. Wilde. Examples of unnecessary surgeries reported to Dr. Wilde in this time period include: (a) four

corpectomy cases in which Dr. Asfora inserted a Bullet Cage or Samba Screw into the vertebral body, a procedure which is unheard of, far outside the standard of care, medically unnecessary, dangerous and off-label; (b) a medically unnecessary and off label multi-level cervical cage that fell apart; and (c) another medically unnecessary and off label multi-level surgery that Dr. Haft had to fix. The doctors presented recent, actual cases of medically unnecessary surgery for financial gain because of Dr. Asfora's inherent conflict of interest.

182. There was no response from administration. It continued to employ, protect and benefit from Dr. Asfora's fraud.

183. On or about February 26, 2016, Dr. Wellman spoke to Rick Schaefer (medical rep) who stated that Dr. Asfora routinely bills his PA's assist in surgery when they do not assist or are not even present. Mr. Schaefer was reporting to Dr. Wellman what he personally observed in the OR when he worked with Dr. Asfora. He asked Dr. Wellman how Dr. Asfora could still be practicing in light of his brazen improper practices.

184. On or about March 4, 2016, Drs, Wellman, Gust and Haft received text messages from the new Chief of Staff, Dr. Laurie Landeen. She said that Dr. John Lee had talked to her about Dr. Asfora and all the complications after his surgeries, the overuse of implants and the improper use of cages. Dr. John Lee sits on Sanford's Board of Governors. Dr. Wellman advised Dr. Landeen that all of these issues had been discussed at length and in detail with Dr. Farritor, Lois Marshall, Dr. Wilde, Dr. Blue, and many others. She said she was unaware of these issues and would investigate. Drs. Gust and Haft confirmed the issues in a separate discussion with Dr. Landeen.

185. On March 7, 2016, Dr. Landeen confirmed that the outside review promised by Dr. Apaas had never occurred. Dr. Landeen instructed the doctors, including Relator Dr. Wellman, to bring Dr. Asfora complications and improper cases directly to her.

186. Dr. Landeen called Dr. Wellman, Dr. Haft and Dr. Gust and asked them to pull examples of Dr. Asfora's aggressive, medically unnecessary cases and multiple level surgeries. She said that she also wanted the names of the patients with aggressive cases that had been sent to Dr. Wilde. Dr. Wellman relayed to Dr. Landeen that he had already sent these examples to Dr. Wilde and he said they were sent to outside review. Dr. Wellman nevertheless verbally discussed the case examples with Dr. Landeen from memory. Dr. Landeen appeared upset and said she would go directly to CEO Kelby with this information herself.

187. Shortly after this exchange of information and her assurance that she would go directly to the CEO, all texts from Dr. Landeen suddenly stopped.

188. There was no further response or explanation of change of course from administration. Sanford continued to employ, protect and benefit from Dr. Asfora's fraud.

Unlawful Kickbacks

189. Dr. Asfora is the 100% owner of Medical Designs, LLC, which distributes the Bullet Cage that Dr. Asfora uses (usually off-label) in almost all of his patients.

190. An entity like Medical Designs is a POD. As the Office of Inspector General has warned, "given the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers, we believe these ventures should be closely scrutinized under the fraud and abuse laws." Letter from Vicki Robinson, Chief, Industry Guidance Branch, Department of Health and Human Services, OIG,

Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (Oct. 6, 2006).

191. Dr. Asfora's POD violates the Anti-Kickback statute as it is 100% owned by Dr. Asfora and since he is the sole user of the Bullet Cage and he uses it exclusively for his surgeries. Every time he uses the Bullet Cage for his patients it is a self-referral.

192. Dr. Asfora is personally financially incentivized to not only use his cages over the competition, but, he is also personally financially incentivized to use his cages as much as possible and to overutilize them. This inherent conflict has led him to perform unnecessary surgeries, to perform multiple level fusions, to use his devices off-label, and to implant his devices in cases where they are not medically necessary.

193. The clear kickbacks here taint every procedure in which the Bullet Cages have been used. Dr. Asfora does not notify his patients of the relationship he has with Medical Designs or otherwise advise them of his 100% ownership in the cage distributor. He also qualifies for no statutory safe harbor.

194. Sanford Health is knowingly complicit in this arrangement. It has been advised of this relationship and the kickback implications on multiple occasions, including by Relator Dr. Wellman as detailed herein. Sanford has also been notified of the numerous medically unnecessary, multi-level cases performed using Dr. Asfora's own cages which are a result of his inherent conflict.

195. Despite having this knowledge, Sanford Health has not disciplined, but has protected and enabled, Dr. Asfora from inquiry, shielded him from discovery by patients and ignored and intimated anyone who reported or spoke out internally about this relationship and its consequences.

Specific medically unnecessary procedures, kickbacks and off-label use

SI fusion indications and coverage determinations.

196. The Samba Screw is designated as a Class II device, "smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)" per its 510(K).

197. Per that CFR definition, the device "may be used for fixation of **bone fractures**, for **bone reconstructions**, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (**traction**) may be applied to the skeletal system." 21 CFR 888.3040(a).

198. It is meant for fractures, reconstructions or to assist traction. Nowhere in the CFR or in Samba Screw's 510(K), is there any indication to use the Samba Screw for fusion or that it is indicated to treat generic sacroiliac joint pain.

199. The local CMS contractor, Wisconsin Physicians Service Insurance Corporation (05901 - MAC - Part A), describes the SI joints as follows in its Local Coverage Determination:

> The sacroiliac (SI) joints are formed by the connection of the sacrum and the right and left iliac bones. The sacrum is the triangular-shaped bone in the lower portion of the spine, below the lumbar spine. While most of the bones (vertebrae) of the spine are mobile, the sacrum is made up of five vertebrae that are fused together and do not move. The iliac bones are the two large bones that make up the pelvis. As a result, the SI joints connect the spine to the pelvis. The sacrum and the iliac bones (ileum) are held together by a collection of strong ligaments. There is relatively little motion at the SI joints. There are normally less than 4 degrees of rotation and 2 mm of translation at these joints.

Local Coverage Determination (LCD): "Percutaneous minimally invasive fusion/stabilization of the SACROILIAC joint for the treatment of back pain" (L36000) (Rev. 2/16).

200. The local CMS contractor covering South Dakota, has issued a Local Coverage Determination regarding SI fusions titled, "Local Coverage Determination (LCD):

Percutaneous minimally invasive fusion/stabilization of the SACROILIAC joint for the treatment of back pain (L36000)." It provides the indications for when SI joint fusion is considered medically necessary and reimbursable by CMS:

> **Indications**
> Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain is indicated for the treatment of SIJ pain for patients with low back/buttock pain who meet all of the following criteria:
>
> a) Have undergone and failed a **minimum six months of intensive non-operative treatment** that must include medication optimization, activity modification, and active physical therapy;
>
> b) Patient's report of non-radiating, unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain;
>
> c) Localized tenderness with palpation of the posterior SIJ in the absence of tenderness of similar severity elsewhere (e.g. greater trochanter, lumbar spine, coccyx) **and other obvious sources for their pain do not exist**;
>
> d) Positive response to the thigh thrust test OR compression test **AND 2 of the following additional provocative tests:** Gaenslen's test, distraction test, Patrick's sign;
>
> e) Absence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorders (e.g. fibromyalgia);
>
> f) **Diagnostic imaging studies that include ALL of the following**:
>
> 1. Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g. tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion;
> 2. **Imaging of the ipsilateral hip** (plain radiographs) to rule out osteoarthritis;
> 3. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain;
>
> g) **At least 75 percent reduction of pain** for the expected duration of the

anesthetic used following an image-guided, contrast-enhanced SIJ injection **on two separate occasions**

LCD L36000 (Rev. 02/01/2016) (emphasis supplied).

201. Additionally, the North American Spine Society ("NASS") published relevant national guidelines dated 6/9/15. Similar to the CMS indications, NASS advises that sacroiliac joint fusion is indicated for the treatment of SI joint pain for patients with low back or buttock pain who meet all of the following criteria:

1. Have undergone and failed a minimum of **6 months of intensive nonoperative treatment** that must include medication optimization, activity modification Sacroiliac Joint Fusion Sep 15 7 bracing and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ, and hip, including a home exercise program;

2. Patient's report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae) localized to the posterior SIJ and consistent with SIJ pain;

3. A thorough physical exam demonstrating local tenderness with palpitation over the sacral sulcus (i.e., Fortin's point at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) **in the absense of tenderness of similar severity elsewhere in the body** (i.e., greater trochanter, lumbar spine, coccyx) and other obvious sources for their pain do not exist;

4. **Positive response to a cluster of 3 provocative tests** (eg., Thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's test, posterior provocation test). Note that the thrust test is not recommended in pregnant patients or those with connective tissue disorders;

5. Absense of generalized pain behavior (eg., somatoform disorders) or generalized pain disorders (eg., fibromyalgia);

6. **Diagnostic imaging studies** that include all of the following: a. Imaging (Plain x-rays or CT or MRI) that excludes the presence of destructive lesions (eg., tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion; b. Imaging of pelvis (AP plain radiograph) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; c. Imaging of the SI joint that indicates evidence of injury and/or degeneration.

7. **At least 75% reduction of pain** for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ **injection on two separate occasions;**

8. A trial of at least on intra-articular SIJ injection (i.e., Cortisone injection). (emphasis supplied).

202. NASS also notes that sacroiliac joint fusion is not indicated in "any case that does not fulfill all of the above criteria."

Medically unnecessary and not indicated SI fusion cases

203. Dr. Asfora markets and uses his Samba Screws in conjunction with his Bullet Cages. He recognizes that unnecessary lumbar fusion will usually cause SI joint pain. Dr. Asfora's typical fraudulent scheme is that he intentionally performs medically unnecessary lumbar fusions in order to use his Bullet Cages and then performs a second medically unnecessary SI fusion using his Samba Screws off-label and not as indicated to address the associated SI joint pain that results from his first unnecessary surgery.

204. Most times, it is only after multiple unnecessary surgeries that these patients are finally referred to Relator Dr. Bechtold.

205. This scheme was verbally confirmed by Dr. Asfora himself. Dr. Bechtold overheard a conversation in the surgical lounge between Dr. Asfora and his surgical representative, Jesse Talcott. They were discussing how they might market the Samba Screw to surgeons across the country and across the world. The question of indications for surgery was asked and Dr. Asfora answered with great enthusiasm the very high percentage of patients having had lumbar fusions that are known to develop SI joint pain. He noted that they will have pain when pressed upon at the SI joint and they have pain when they sit down in the office. That generic hip pain is his stated surgical indication for Samba Screw use, as instructed

to his sales representative and in distinct conflict with the actual indications for the procedure as listed above.

206. As a hip specialist, Dr. Bechtold has had numerous occasions to see patients that have had SI fusions or lumbar surgery by Dr. Asfora only to have continued complaints of pain that prompt an evaluation for hip pathology as the source of ongoing pain. Most often, the patients will report to Dr. Bechtold that the pain could not be a result of Dr. Asfora's surgery because Dr. Asfora had assured the patients that their "surgery was perfect, so it must be your hip."

207. Dr. Bechtold's experience has been that the vast majority of these patients with SI fusions continue to complain of pain in the SI joint. The same is often true of those that have had lumbar fusions. Some are found to have hip pathology producing symptoms that they indicate were the same symptoms that caused their spine or SI interventions, only to later be alleviated by total hip arthroplasty. In other words, the problem was clearly in their hip all along and the lumbar fusion was totally medically unnecessary.

208. Other times, there appears to be no hip pathology that could account for their ongoing symptoms whereas the lumbar spine or SI joint continues to be a problem without any willingness on the part of their initial surgeon, Dr. Asfora, to diagnose or treat the pathology.

209. A few of these patient examples are given in detail as examples of the typical cases seen by Dr. Bechtold and the pattern of fraud.

Patient [redacted]

210. Patient [redacted] is a representative example of the types of medically unnecessary, off-label, not medically indicated and patient safety scenarios Dr. Bechtold routinely sees from Dr. Asfora. Medicare Patient [redacted] (DOB: [redacted]/1946) was sent to Dr. Bechtold to evaluate a

painful hip as a source of ongoing pain after numerous surgical interventions. Patient reported a history of greater than 20 years of pain in the left hip, pelvis and buttock. His case represents a series of medically unnecessary surgical decisions and procedures by Dr. Asfora, a not atypical series of clinical events seen by Dr. Bechtold when evaluating Dr. Asfora patients.

211. Patient [redacted] initially saw Dr. Asfora on [redacted]/12 for a chief complaint of back pain and there is notation of multiple lumbar surgeries from L3-S1 by other surgeons. He has had numerous additional interventions, injections and treatments for his chronic back pain and ultimately had injections of the bilateral SI joints which provided "4 days relief." The initial note indicates that he is there for evaluation of a complaint of back pain and there is notation of "failed extensive conservative therapy" and "therefore would like to undergo surgical fixation" though his long term issue and conservative management has been for a known failed back type syndrome rather than for any SI pathology.

212. Patient [redacted]'s physical exam is noted negative for Faber (which should elicit SI pain if there was SI pathology) but instead was pain with "finger test" and SI joint pain.

213. There were no diagnostic imaging studies or at least a 75 percent reduction of pain after 2 separate SIJ injections, as required and indicated by the CMS contractor. LCD L36000 (Rev. 02/01/2016).

214. Instead, the very limited exam and the briefest mention of SI pain led to a Dr. Asfora plan for staged bilateral fusions of the SI joints. This evaluation is documented entirely by the PA, with "Patient seen and reviewed with Dr. Asfora. He is in agreement with the above."

215. There was no medical indication for SI fusion for this patient.

216. Nevertheless, patient [redacted] underwent his staged bilateral SI joint fusions with 3 Samba Screws used not as indicated and implanted on each side on [redacted]/13 and [redacted]/13.

217. Less than a month after surgery, the patient continued with his original complaint of low back pain as documented in an office phone call dated [redacted]/13. The patient is documented to have questioned this pain. He asked if this pain at the base of his spine is from fusing the SI joints. Michele Healy, PA responded that the pain is ok given that he had bilateral SI fusions. A phone call again indicates pain at the "bottom of the spine in a 3 inch area that is getting worse, is this part of the healing process?"

218. On [redacted]/13, there was an office encounter documented, "Following fusion of bilateral SI joints symptoms have resolved, however 2 weeks ago patient began experiencing progressively worsening low back pain. States low back pain at the top of the sacrum radiating posterior aspect of bilateral lower extremities to knee. Straight leg raise is negative bilateral. Tender top of sacrum. Most likely related to facet joint pain at the L2-L3 level." This patient was told this although recently he had been told that pain in that region is normal from fusion of the SI joints. MRI is also noted to be normal in the area of the patient's actual pain at that visit. "If patient receives transient relief from the injection will proceed with a L2-L3 fusion. Unclear the source of patient's sacral pain."

219. In sum, the patient was evaluated for ongoing pain near the site of a recent surgery, was told recently that such ongoing pain was expected due to surgery, has other documentation that his pain from the original SI problems has resolved when it had not been, and ultimately is started down a pathway to provide additional surgery to an area potentially unrelated to his complaints of the current visit but consistent with the complaints of the initial visit that led to the unnecessary SI fusions. There is no documentation from the surgeon to

indicate what rationale lead him to look for pathology remote to the patient's main area of concern.

220. The next day, patient [redacted] underwent bilateral L2-L3 facet injections. His wife called the office on [redacted]/13 reporting that "patient has gotten some relief and patient would like to schedule surgery, in town [redacted]."

221. Therefore, the patient has complaints remote from the site, exam finding documented remote from the site, negative exam finding for radicular exam findings (negative straight leg raise) and "some relief" from injections to the facet joints and yet is quickly scheduled for surgery on [redacted]/13 just two months from his last intervention for which he was told it is normal to still have some pain as he has described. This additional surgical intervention was not medically indicated and should not have been reimbursed by CMS.

222. Patient [redacted] then had:

> "(1). Bilateral L2-L3 decompressive laminectomy, facetectomy, foraminotomy, diskectomy, posterior lumbar interbody fusion with Bullet Cage and autogenous bone and posterolateral fusion with autogenous bone.
>
> (2). Removal of old instrumentation of the left L3 pedicle
>
> (3). Left L2-3 percutaneous pedicle screw fixation."

223. Strangely, in the indication for surgery there is cited "failure of conservative management" of which there was none documented nor time for any to really be accomplished in the short amount of current symptoms. This failure of conservative management must have been fabricated in the record in order to justify CMS reimbursement as required. However, even this fabrication was not enough to document, let alone comprise, the requisite conservative management. Under the applicable Local Coverage Article a "physician statement that conservative treatment measures were completed is not supportive in and by itself;

contractors do require the documentation of these measures." Local Coverage Article: SPINAL FUSION Services: Documentation Requirements (A53973) (Effective date: 10/1/15).

224. Two of Dr. Asfora's devices were inserted during this medically unnecessary surgery.

225. In a phone call dated [redacted]/13, the patient's wife indicates "[redacted] is not improving. Would like swing bed."[redacted]/13 "patient still having a lot of pain on left side." On [redacted]/13 Dr. Asfora comments "patient undergone remote L3-S1 fusion by another surgeon. I have performed more recently bilateral SI joint fusions and an L3 fusion with Bullet Cage and pedicle screws. Patient continues to experience some discomfort in the mid back area of his remote surgery," "but pain over SI joints markedly improved." Of course, there had been no severe or pervasive SI pain before seeing Dr. Asfora.

226. On or about [redacted]/13, a phone call indicates yet again continued low back pain and bilateral buttock pain for patient [redacted]

227. On or about [redacted]/13, patient [redacted] had an office visit. Dr. Asfora mentions the patient has a history of "known failed back" (a term often used to indicate continued pain despite surgical interventions). … Patient complains of lower back pain over the area of previous surgery by Dr. Habasi." With this note, Dr. Asfora uses the pain as an indication for surgical insertion of a Synchromed pain pump. One might interpret from the notes that the symptoms at this time are the exact same symptoms that led to the last surgical intervention, but now prompt the insertion of a pain pump that is inserted by Dr. Asfora [redacted]/13 for a diagnosis of "failed back/post laminectomy syndrome." There is no further consideration of the recent surgery as a source of pain despite an x-ray on [redacted]/13 that shows lucency around the Bullet Cage on the right at L2-L3. This lucency is likely consistent with non-union and poor

device placement, and is a clear potential source of ongoing pain worthy of further diagnostic and clinical consideration.

228. Despite this, Dr. Asfora has now performed the third medically unnecessary procedure on patient [redacted]

229. On or about [redacted]/13, a phone call indicates persistent low back and right lower extremity pain including right hip pain radiating to the anterior thigh. This prompts an MRI which shows osteoarthritis of the right hip and right hip bursitis and ultimately a request for orthopedic evaluation. Two years pass.

230. On or about [redacted]/15, the patient has a documented phone call regarding "increasing need for boluses of morphine sulphate and more pain. Pain is just like prior to SI fusion. Advised will talk with Justin Tuntland and possibly do right SI injection." Justin Tuntland's (Certified Nurse Practitioner) recorded response the next day reads: "Could have irritated right SI even though it is fused. Do right SI injection to see if it will settle everything down." Patient's wife responds that he is being admitted for pneumonia.

231. On or about [redacted]/15, a phone call documents patient concerns of "numb buttocks and loss of bowels. Advised to go to the ER. Wife asks of ongoing SI joint pain. Wife advised that we already did SI joint fusions bilateral, and typically they will not inject into a fused SI joint, so the only option would be to have patient's pain pump elevated. The last time we saw Dr. Asfora he did tell us that injections would not work in a SI joint that he had already fused."

232. Of note, there are numerous recurring complaints by the patient and his wife about persistent and ongoing SI joint pain while Dr. Asfora's clinical notes and indications for

further surgeries consistently note complete resolution of the SI symptoms. Also noted is the injection ordered into the fused right SI joint for persistent pain previously.

233. On or about [redacted]/15, patient phone call indicates being in the transitional care unit for the month of September for recurrent pneumonia and now on tube feedings. Also a note that pain has been increasing ever since the pain pump was placed in August. His record notes that the patient is depressed.

234. On or about [redacted]/15, there is notation by PA Michele Healy in this patients' medical record that:

> "surgery planned for tomorrow bilateral L1-L2 discectomy and PLIF with unilateral pedicle screw fixation as patient has been seen and worked up by Justin (relatively new CNP). Recommended surgery and now patient needs to discuss with Dr. Asfora. No change in symptoms since previous eval and no change on physical exam. Dr. Asfora discussed images with patient and surgical procedure offering no guarantee that procedure will provide the patient with improvement of symptoms. If pain continues following procedure will need to continue to control pain with Synchromed infusion system patient currently has implanted."

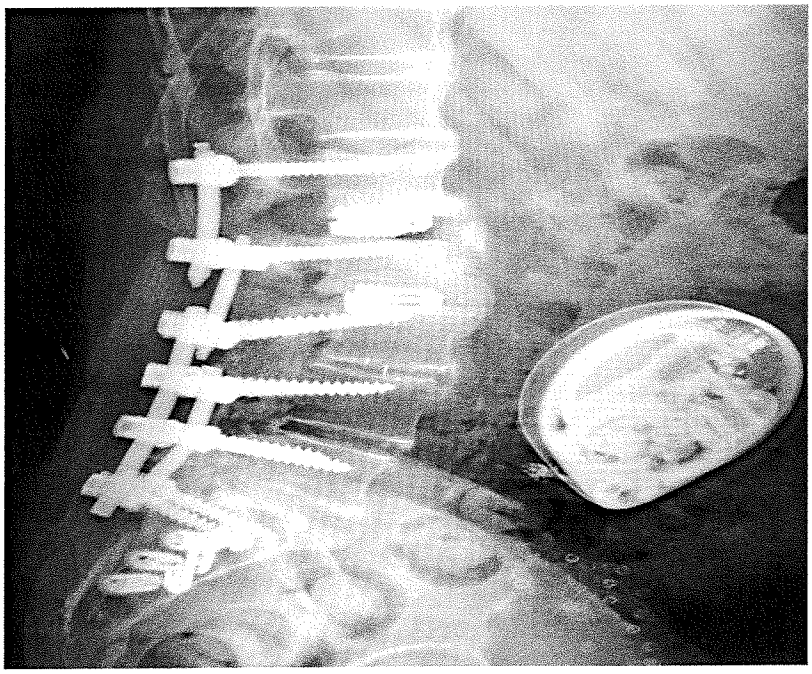
235. Thus, the patient was offered surgery based on the evaluation of the CNP with no real expressed expectation of improvement. The diagnosis for this third surgery is yet again "failed back syndrome." The patient therefore underwent similar surgery for L1-L2 that he had for L2-L3 that did him no good and the continued pain was blamed on the previous failed surgeries. With this third surgery, there is preoperative disclaimer included that the surgery might not help. An additional two Dr. Asfora devices are inserted on this occasion for this medically unnecessary and not indicated procedure.

236. Not surprisingly, with all of these medically unnecessary and failed surgeries, on or about [redacted]/16, patient [redacted]'s wife called to report continued severe pain and requested

steroids saying "he is in so much pain, he cannot function." The recommendation is to go to the ER for pain control and to use his available pain meds and if not better call back and maybe CNP Justin Tuntland will prescribe steroids. His pain medications are subsequently increased.

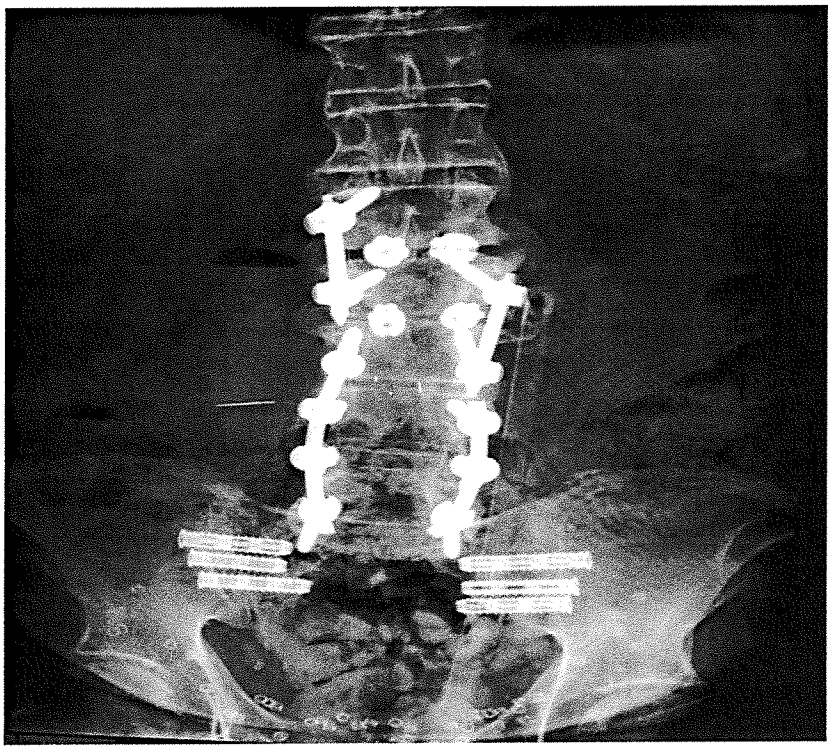
237. In a troubling pattern that repeats itself with all of Dr. Asfora's medically unnecessary surgeries, on or about [redacted]/16, a note from Justin Tuntland reports that "Dr. Asfora read x-rays – **well placed instrumentation** and no issues seen." (Emphasis supplied). The wife again reports continued pain in back and legs.

238. The below x-ray[2] of the lateral view demonstrates the lack of any mechanical benefit from the upper cages in particular as they barely even contact the L2 vertebral body:



The front view shows the extent of this surgery:

[2] Patient names have been removed or redacted from all films and chart images to protect patient privacy in this filing.



239. On or about [redacted]/16, patient [redacted] received another injection of the left SI joint despite previously documented "complete resolution of symptoms" and indications that one would not inject the fused SI joint.

240. If the symptoms had been resolved as noted in the medical record, then there was no medical necessity for a SI injection. If they had not been resolved, then the medical chart was fabricated. Both result in fraudulent claims to the government.

241. On or about [redacted]/16, the medical records note a phone call report of continued complaint of SI joint pain.

242. Finally, patient [redacted] saw Dr. Bechtold in [redacted] 2016 and patient described a number of areas of pain. An injection was done in to the left hip bursa and arrangement was made for an injection into the left hip which led to resolution of the left hip area pain. The right hip began hurting again similar to 2013 at the time of documented right hip arthritis by MRI.

The left hip pain resolved after injection. The patient has now successfully undergone right total hip arthroplasty with complete resolution of symptoms after first confirming the diagnosis of hip pathology with intra-articular injection and provocation of hip pain on hip exam. There remained, however, gross concern about the spine as a major contributing pain generator.

243. In summary, it is somewhat difficult to follow [redacted]'s surgical indications as they conflict in the chart with the documented patient complaints. There is no documentation by Dr. Asfora himself just prior to surgery to explain the indications, as is required by CMS. Instead, there is a fairly rapid progression of surgeries with little time to allow for the cited and conclusory "extensive" or "failed" conservative management and many are based on a transient relief of pain remote to the areas the patient actually complains about in the documentation. The patient phone calls represent the best documentation and seem to be contrary to that documented by Dr. Asfora or his assistants as justification for surgeries. Ongoing problems and pain are not attributed to surgeries done by him, rather they are blamed on the prior surgeons after the fact. The patient has had numerous complications from the pump and narcotic administration and no resolution of the symptoms that led to his numerous unnecessary interventions.

244. In summary, after two years, there is no well documented clinical indication for the bilateral SI joint fusions, or for the additional 2 surgeries, and this patient has suffered as a result. This is just a representative example, there are many others similar to this.

245. At all times, the decisions and actions of Dr. Asfora's clinical staff contained herein were made in consultation with him and at his instruction and with his supervision.

PATIENT [redacted]

246. As another representative example of the types of medically unnecessary, off-label, not indicated and risk to patient surgeries Dr. Bechtold routinely sees from Dr. Asfora, patient [redacted] is a [redacted]-year-old male Medicare patient (DOB: [redacted]/1940) sent to Dr. Bechtold for evaluation of left hip pain on [redacted]/16. He was found to have some arthritis of the hip, but complained more about ongoing pain in the left lower back and sacroiliac region.

247. Dr. Bechtold has thoroughly reviewed this patient's relevant medical records in an attempt to treat his ongoing pain. On or about [redacted]/15, his regular physician noted that the patient's "back went out yesterday." On [redacted]/15, an MRI of his lumbar spine was obtained. The MRI results would not at all be atypical of the aging spine and many asymptomatic patients in this age group might be found to have similar findings. At the time, the radiologist recommended clinical correlation for that very reason, meaning that although there are some abnormal findings, they in and of themselves have little to no clinical meaning without clinical history or exam findings consistent with that pathology.

248. On or about [redacted]/15, there is an office note with Dr. Asfora indicating "a large disc herniation on the left of L5-S1. Pt has a deep stabbing pain which radiates down his whole left leg and stops at his ankle. His back pain is worse than his leg pain." There is a plan for a left L5-S1 discectomy, TLIF with right pedicle screw placement.

249. Conventional wisdom and the standard for disc herniation, even with radicular symptoms, is that a majority will resolve with conservative management and often a directed injection may be sufficient. The MRI also shows mild degenerative change which would not require a fusion.

250. Rather than allowing for a meaningful time of conservative management, there is a surgical date of [redacted]/05 just 17 days from onset of symptoms. The surgical indication in the operative note from Dr. Asfora indicates a "**long history** of severe low back and left lower limb pain. MRI of the lumbosacral spine revealed a large disk herniation at L5-S1 level associated with cauda equina and left S1 nerve root compression. In view of **failure of conservative management**, surgical intervention was medically indicated." (Emphasis supplied).

251. This was fabricated. There had been no "long history of sever low back pain" and no "failure of conservative management" in the short 17 days from symptom onset to unnecessary fusion surgery.

252. However, contrary to Dr. Asfora's justification, and based on the documented record for this patient, [redacted] went from a phone call with back spasms and back pain to a fusion and decompression 17 days later with no conservative management or trial and a significant discrepancy between the formal MRI by a radiologist and Dr. Asfora's interpretation for surgical indication. The MRI "reason for exam" is "lumbar back pain." This is clearly inaccurate and fabricated documentation from Dr. Asfora combined with improper and extremely aggressive medical decision making.

253. National standards and guidelines speak to the trial and use of nonsurgical or conservative management before surgery, particularly in the elderly population. These are repeatedly disregarded by Dr. Asfora with his elderly patients. The American Academy of Orthopedic Surgeons, for example, provides the following guidance:

> "In the majority of cases, a herniated lumbar disk will slowly improve over a period of several days to weeks. **Typically, most patients are free of symptoms by 3 to 4 months.** However,

some patients do experience episodes of pain during their recovery.

Nonsurgical Treatment
Unless there are neurological deficits — muscle weakness, difficulty walking — or cauda equina syndrome, **conservative care is the first course of treatment.** Because it is not clear that nonsurgical care is any better than letting the condition resolve on its own, the focus is on providing pain relief.

Common nonsurgical measures include:

Rest. Usually 1-2 days of bed rest will calm severe back pain. Do not stay off your feet for longer, though. Take rest breaks throughout the day, but avoid sitting for long periods of time. Make all your movements slow and controlled. Change your daily activities so that you avoid movements that can cause further pain, especially bending forward and lifting.

Anti-inflammatory medications. Medicines like ibuprofen or naproxen may relieve pain.

Physical therapy. Specific exercises can strengthen your lower back and abdominal muscles.

Epidural steroid injection. In this procedure, steroids are injected into your back to reduce local inflammation.

Of the above measures, only epidural injections have been proven effective at reducing symptoms. There is good evidence that epidural injections can be successful in 42-56% of patients who have not been helped by 6 weeks or more of other nonsurgical care.

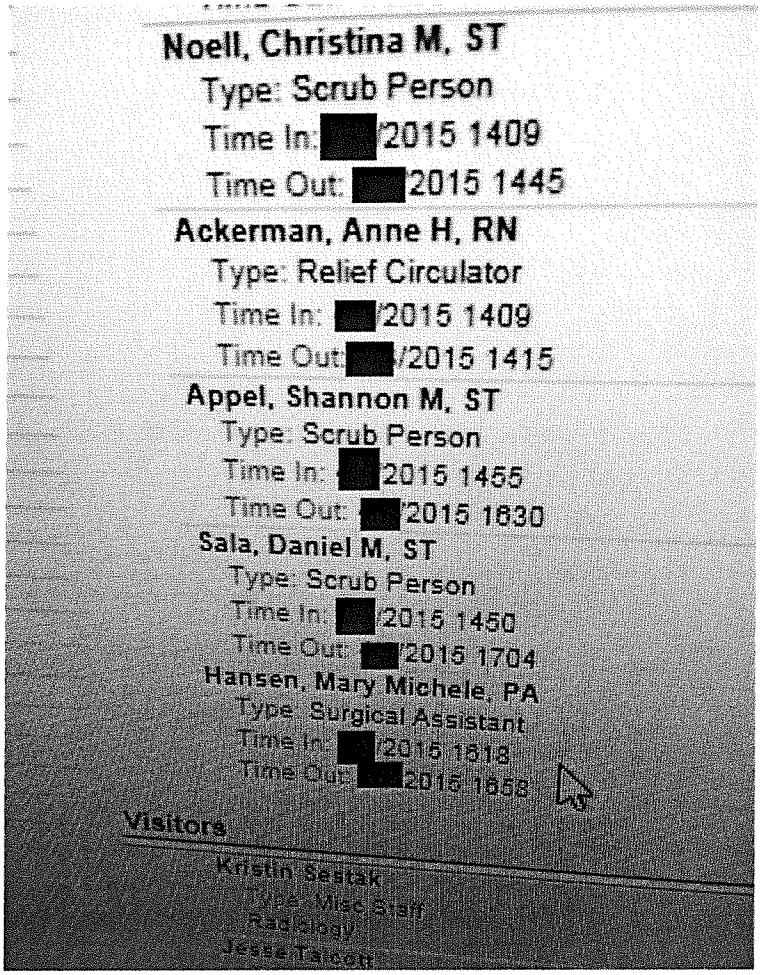
Overall, the most effective nonsurgical care for lumbar herniated disk includes observation and an epidural steroid injection for short-term pain relief.

Surgical Treatment
Only a small percentage of patients with lumbar disk herniations require surgery. Spine surgery is typically recommended only after a period of nonsurgical treatment has not relieved painful symptoms.

American Academy Orthopedic Surgeons, "Herniated Disk in the Lower Back" Available at: http://orthoinfo.aaos.org/topic.cfm?topic=a00534 (*last accessed* 8/2/16) (emphasis supplied).

254. These guidelines are provided and would apply even in the setting of true radicular symptoms, or symptoms of pain going into the lower extremity, rather than the less severe and localized low back pain that patient [redacted] was actually describing.

255. This is also an example of fraudulent billing for a PA as an assistant-to-surgery. The procedure start time was 15:12 and the time of closing documented in the nursing record is 16:24. Michele Hansen time-in is documented at 16:18 and out at 16:58 consistent with being called in to provide wound closure only. Billing would have to be separately identified, but this would be an assist that the circulator would be required to bill as a first assist fee despite being there for closing a wound only. A shot of the nurse's surgical log shows this:



256. Of note, Dr. Asfora's sales representative, Jesse Talcott, is also listed among the "visitors" at this surgery.

257. On or about [redacted]/15, patient [redacted] presents for a 2 week follow up visit and a report of "no pain radiating down his legs since surgery, but he is having significant low back tightness and pain."

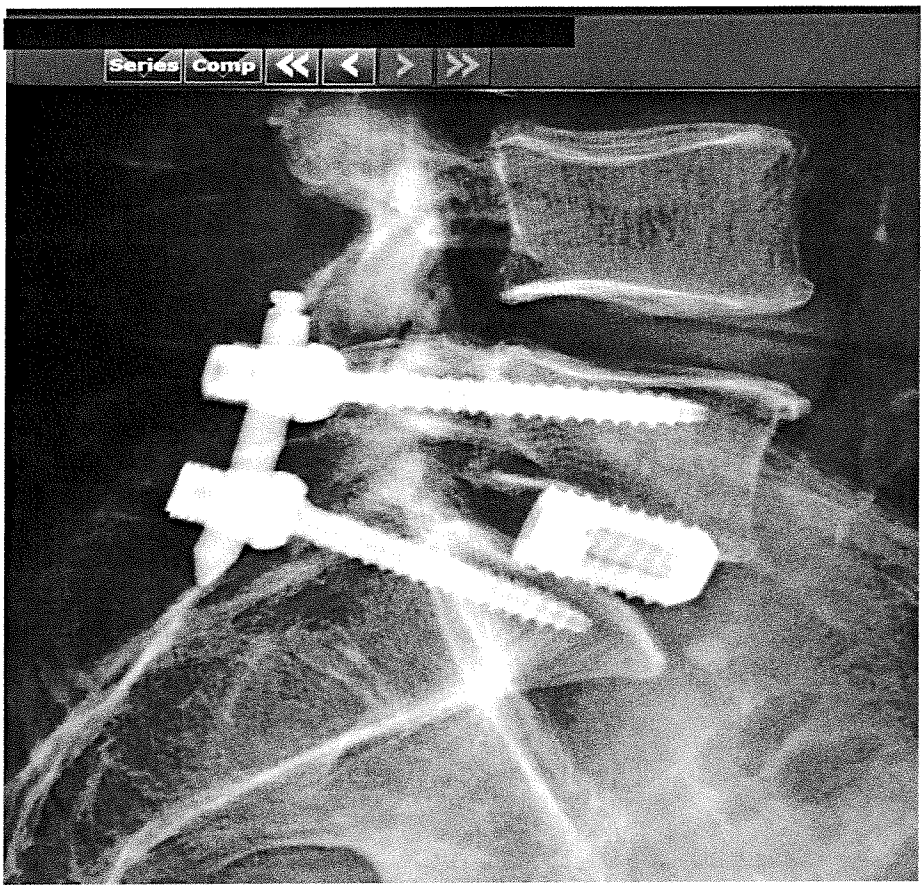
258. On or about [redacted]/15, a call into the office reports a new pain across his lower back left-to-right. Medication recommendations are provided at this time. Increasing pain several weeks after surgery would be a concerning feature that should be addressed with

further exam, imaging, labs and follow-up. There appears to be no investigation in the record as to the reason for increasing pain.

259. On or about [redacted]/15, there is a six-week follow-up and the patient expresses concern for ongoing left lateral low back pain. He also had a DVT (deep vein thrombosis) in the leg after surgery.

260. The assessment and plan continues in the usual Dr. Asfora pattern, stating that "images reviewed with pt and show **well placed instrumentation**. Discussed with patient that his left lateral back pain is probably related to left cluneal nerve entrapment. Will order left cluneal nerve injection." (Emphasis supplied).

261. X-rays from right after surgery, [redacted]/15, call seriously into question any possible mechanical value of the Bullet Cage on this occasion with limited contact with the endplate of S1, certainly not into the bone but rather appearing to rest upon it. These xrays contradict Dr. Asfora's written note in the medical record that the device was "well placed":



262. A [redacted]/15 office note refers to DVT and continued pain, "he has no leg pain but has significant back pain. Pain medications [have] been problematic and he has not responded to trigger point injections. He's having trouble sleeping."

263. Another office call, on [redacted]/15, notes the patient's concerns of ongoing left low back/upper buttock pain. [redacted] "states that Dr. Asfora told him that he has a 'trapped nerve'." A response from Krista Seurer PA-C indicates "too early to do MRI. Let's get a CT lumbar and plan xrays and make sure hardware is ok." Those CT scan images show a halo all around the Bullet Cage which is defined typically as a concern for loose hardware. The PA has appropriately considered that as a very real potential source of ongoing pain and dysfunction as documented in the note. However, there is no follow-up on this.

264. On or about [redacted]/15, Dr. Asfora's PA, Justin Tuntland, CNP's, notes indicate, "Pt presents due to ongoing left low back pain and left buttock pain since he had a Left L5-S1 TLIF on [redacted]/05. He notices increase pain when he flexes. The pain is constant." Assessment and Plan is "Low back pain." DEXA scan and NM bone scan ordered to check bone density and an injection of the left SI joint is ordered "since he is tender in the left SI." An SI injection is ordered although there has never been mention from the patient of pain in that region.

265. A [redacted]/15 phone call documentation indicates that the patient states "that he got relief from back pain [than] the buttock pain. . .Pt is wanting to do anything to get relief, so he is all for SI joint fusion if Dr. Asfora thinks that helps." Response [redacted] from Justin Tuntland is "discussed pt with Dr. Asfora. It is interesting that his back pain improved after an SI injection and not his buttock pain. We can proceed with SI fusion if pt wishes, but Dr. Asfora is giving the surgery a 70% chance of relieving his pain due to the atypical result of the SI joint injection."

266. At this point, Dr. Asfora has not examined the patient although SI joint fusion is being discussed and a percentage of success has been given to the patient. There is a CT scan showing findings that should be concerning for failed hardware if Dr. Asfora had looked at them in an unbiased way.

267. Moreover, patient [redacted] has had complaints of back pain primarily and an injection was done because he was tender when pushed in the SI region. Those who examine patients find that to be an incredibly common exam finding and is not in and of itself an indication for an SI injection, let alone for fusion, which has been provided above, before even considering a surgical intervention to be indicated. The Local Coverage Determination, *supra*,

also requires far more than simply a finding of tenderness when pressure applied to the SI joint before it will reimburse for SI joint fusion.

268. In the case of [redacted], the steroid provided no benefit in the SI area, but the systemic effect of steroid helped his back pain somewhat, a fact that should not be overwhelmingly surprising and the test confirmed that the patient does not have pain coming from the SI joint. At this point, there is very real concern of a problem from the original surgery, but no indication of a need for more surgery addressing the SI joint. It is only found by a provider pushing on the area. There is no clinical indication for the procedure, but more importantly there are any number of clinical reasons to look deeper into causes of pain from the original surgery that was not medically indicated.

269. On or about [redacted]/15, the nurse communicates the plan to the patient based on Justin Tuntland's response. The following paragraph is extremely telling in the patient's description to the nurse:

> "Pt has low back pain that goes straight across his back, and it is mostly on his left side. Pain has never gotten better since surgery, which was [redacted]/15. Pt states that he has no pain that goes into his hip, groin or down his leg, it is strictly in his low back. The pain starts on the left side and radiates across his low back. And when he sits, as long it is a straight back chair, he has no pain with sitting. Pt is wanting to know if he needs to be seen again, and he was told that I did not feel that was necessary at this point. Pt was asked if he has done PT? **Pt has not done any PT(u/s heat, massage, electrical stimulation) or trigger point injections.** Pt keeps saying the pain is more so in his back than in his buttock, and again the injection did not touch his buttock pain, but made his back pain better. **Pt doesn't want to have SI joint fusion, if Dr. Asfora doesn't feel that is the problem.** Please advise."

(emphasis supplied).

270. Justin Tuntland CNP's computer generated response is "Pt can have PT with heat, massage and ultrasound" and nurse documents: "Pt aware and placed order for PT. Gave pt number for PT solutions at Sanford. Pt aware if Pt doesn't help, we would recommend SI joint surgery."

271. In other words, the patient had ongoing concerns and requests for examination and evaluation by his surgeon for ongoing problems in the surgical area and reiterated that the SI joint injection did not help him. His surgeon still does not examine him.

272. On or about [redacted]/15, the patient is seen in the office with Justin Tuntland CNP confirming the above yet again, including lack of response to SI injection for buttock pain and ongoing left low back pain. A plan is made for repeat SI injection.

273. A [redacted]/15 phone call as documented by Tracy Pepin, HUC indicates: "Had an injection last Wednesday and was told if the shot did not work to call back and he is calling to say that the shot did not help and the pain is still there." Jennifer Schiltz forwards a message to Justin Tuntland, CNP based on that patient report as follows: [redacted] "is s/p left Sacroiliac joint injection on [redacted]/15. He had good pain relief for 2 days. He's asking if surgery is recommended?" Justin Tuntland response is "Since pt received slight relief with the injection, he can expect about the same relief with the surgery. If he wishes, we can proceed with starting the surgical process of a Left SI joint fusion."

274. Therefore, two weeks later, on [redacted]/15, patient [redacted] had SI joint fusion. The noted preoperative diagnosis was "left sacroilitis." This procedure is not medically indicated by any clinical parameter. It was not indicated and was not reasonable or medically necessary. It also should not have been reimbursed by CMS regulations or under the applicable Local Coverage Determination(s) as it was not indicated based on the applicable LCD due to, among

other things: absence of failed conservative treatment for six months, absence of localized SI joint pain reported by patient, absence of positive responses on standardized tests, and absence of at least 75% reduction of pain after SI joint injections on two, separate occasions.

275. The indication from Dr. Asfora for the procedure is: "The patient now presents with pain over the left sacroiliac joint. Left SI joint injections transiently alleviated his symptoms. For this reason, we felt that a left sacroiliac joint fusion was medically indicated." This is a fabricated justification. For, the record has the patient repeatedly explaining that there has been no benefit in that region from SI injection and that his problem remains in the area of his lumbar surgery. Most of the surgical decision making process has happened via phone call with what appears to be misrepresentation of the patient's complaints and concerns. This statement is a fabrication by Dr. Asfora to suggest a proper medical indication that clearly doesn't exist and contradicts the documentation directly available in the medical record.

276. Based on the records, these are not indicated, not medically necessary, and overly aggressive and risky surgeries. The patient suffered pain, underwent unnecessary procedures and developed a blood clot after surgery which would have been avoided without surgery given the fact that the patient has no prior history and this clot would be considered provoked by the physiologic changes of surgery.

277. There is no doubt based on documentation that the SI joint fusion was not medically indicated. Despite the patient's ongoing misgivings and even stated desire to avoid the surgery unless completely needed, he went through with it.

278. The patient faced more harm as a result of the second (SI fusion) surgery. He suffered large blood clots in the lungs as a result of this surgery. Typically, elective surgery is

handled very carefully in the circumstance, like this, of a recent clot and only done if truly necessary.

279. This unnecessary SI fusion surgery directly threatened the patient's life.

280. Shockingly, a note by Justin Tuntland CNP on [redacted]/16 indicates:

> "Pt presents for a 6wk follow up after a left SI joint fusion. His SI pain has resolved, but he has developed new left low back pain which is worse when standing, bending and better when sitting. He describes his left low back pain as a achy pain with no radiation."

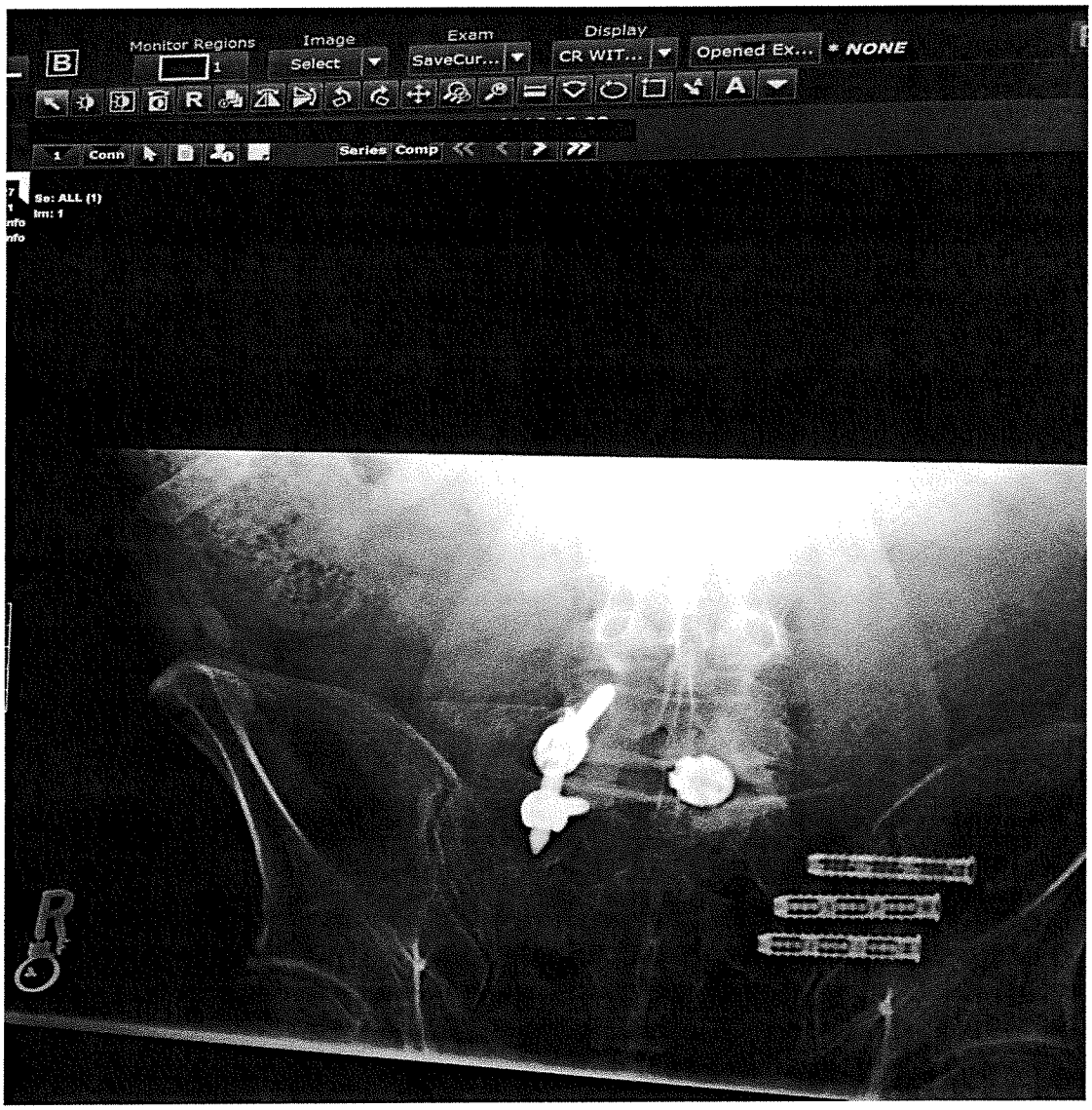
In other words, the SI pain he never experienced has "resolved" and now there is new pain in the back according to the records. Of course, the pain is not "new," but well documented repeatedly since the time of the lumbar surgery. Dr. Asfora nevertheless is still discussing yet more intervention.

281. Tuntland also noted on [redacted]/16 that, "as for his new back pain, we would like to offer pt an injection, however, he is on Coumadin at this time for blood clots and we will have to wait until his blood stabilizes. Pt will call when he is cleared for an injection." Again there is no documentation from Dr. Asfora. The patient has not had further workup or consideration of the pain that he has complained of since the time of his first lumbar surgery.

282. The patient was sent to the spine center for chronic low back pain. A CT scan review at that time indicates avascular necrosis of the left femoral head and bilateral hip joint arthritis. At this point, it would be difficult to determine if the findings of hip pathology were related to his initial presentation of back pain. It is not difficult to say clinically, however, that these symptoms would have likely sorted themselves out after a period of proper conservative management and careful examination.

283. The patient was sent to Dr. Bechtold for evaluation of the left hip avascular necrosis, but after hearing the patient's history and viewing images it was immediately obvious that the patient had a more pertinent issue in the left lower back related to his surgery with Dr. Asfora and was sent for second opinion by another spine provider, Dr. Geoff Haft. Dr. Bechtold saw plain x-rays of the spine [redacted]16 showing obvious halo around the "Bullet Cage" on the left along with the 3 fusion devices in the SI joint. This radiographic finding was immediately concerning to Dr. Bechtold as an indication of a failed fusion and source of ongoing pain since shortly after his lumbar surgery. It also again highlights that the SI fusion was not in any way medically indicated.

284. On review, Dr. Haft commented, "There is a pelvis x-ray from [redacted]16, which is reviewed. There is a metallic interbody spacer at L5-S1. There is some radiolucency around the spacer raising the question of possible pseudoarthrosis. There are three metallic implants across the left SI joint as well. . . There is obvious loosening of the cap on the L5 screw also suggestive of pseudoarthrosis":



285. A CT scan review from [redacted]/15 also indicates the **loose cap** and lucency around the cage suggestive of pseudoarthrosis. Final evaluation and assessment confirms L5-S1 **nonunion** and ongoing, severe, limiting pain in the left lower back as a result.

286. These findings are all quite indicative of a failure of fusion that should be noted by any person who diagnoses or treats spine pathology, especially in the setting of the patient's ongoing complaints and symptoms. Dr. Asfora clearly did not choose to consider the patient's

actual symptoms in the context of a glaringly obvious set of radiographic findings and he instead fabricated "well placed" hardware in the medical record

287. In summary, it is clear that an aggressive approach to a herniated disc with fusion rather than a period of conservative, non-surgical treatment, or even the more medically indicated simple decompression led to a prolonged period of pain and dysfunction as a result of the unnecessary fusion. There was an unwillingness on the part of Dr. Asfora to see the patient and evaluate the actual site of pain. He interprets his imaging and instrumentation as without problem, though it is quite evidently problematic. Additional unnecessary surgery is done on the SI joint again without appropriate surgical indications. This results in major, life threatening complications and an ultimate need to have other providers identify and treat the failed surgery. He required surgery from the back, being turned for surgery through the abdomen and finally repeat surgery on the back in the same setting in order to address the problem. At the time of this documentation he remains in the recovery period from that revision surgery.

288. In all of these surgeries, Dr. Asfora used and implanted his own medical devices, from which he personally profited.

289. Unfortunately, the case of patient [redacted] is simply another example for illustrative purposes, but is by no means a unique clinical scenario as seen by Dr. Bechtold in his evaluation of patients presenting for hip pain evaluation that have been operated on by Dr. Asfora. It again shows the pattern of shifting blame for problems or not noting the issues of his surgical interventions. These patients suffer, they do not benefit. The only benefit from these surgeries clearly was to Dr. Asfora as he was able to implant 3 Samba devices into the SI joint

and one "Bullet Cage" into the spine where none of these were medically necessary or indicated based on the records.

290. At all times herein, the decisions and actions of Dr. Asfora's clinical staff were made in consultation with him and at his instruction and with his supervision as ultimately documented in their notes.

Patient [redacted]

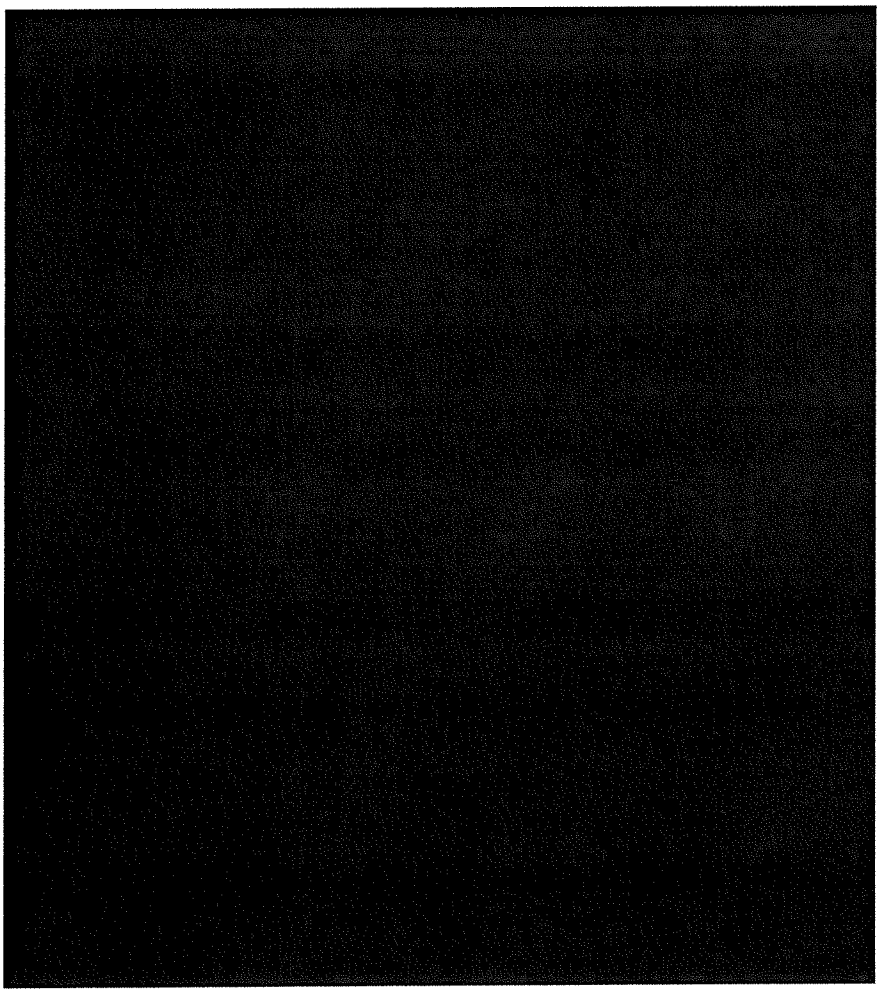
291. As another representative example of the types of medically unnecessary, off-label, not medically indicated and patient safety scenarios Dr. Bechtold routinely sees from Dr. Asfora, Dr. Bechtold in this case was asked to evaluate Medicare patient [redacted]'s hip pain. He saw her on [redacted]/16. This patient has a prolonged history of back and buttock pain and narcotic use at high levels. Dr. Bechtold thoroughly reviewed her history and medical records as follows.

292. Disabled Medicare Patient [redacted] (DOB: [redacted]/1963) was seen by Dr. Haft on [redacted]/10 for her ongoing thoracic and lower back pain after a lower lumbar one level fusion by Dr. Wellman in 2006. At the time of Dr. Haft's visit, she was found to have no pathology of the spine that would need or benefit from further lumbar surgery. His note states:

> "Discussed with the patient and her husband that in reviewing her x-rays and MRI scans I do not see any surgical abnormality causing her mid thoracic or back pain. There is no stenosis, nerve impingement, disk herniation, or stenosis. There are no fractures in her spine. Previous fusion surgery appears to be solidly fused at the L4/5 level without any complications of hardware. Discussed that the plan would be symptom treatment management and this would include possible referral to Dr. John Hansen" (pain doctor).

293. Nevertheless, patient [redacted] had a fusion of her left SI joint by Dr. Asfora on [redacted]/12. Dr Asfora subsequently performed a multi-level, T12-L4, TLIF with right sided pedicle screws on [redacted]/12 for what is described as "progressive scoliosis" with spondylolisthesis at T12-L1, L1-2, and L2-3 as well as L3-4. Four of his Bullet Cages were used in this multi-level fusion.

294. Patient [redacted] continued to have pain and dysfunction despite extensive narcotic use including Oxycodone, diazepam, MS ER 60mg and fentanyl 100mcg patch as of [redacted]/16. She describes her pain "from her shoulder to her lumbar spine:"

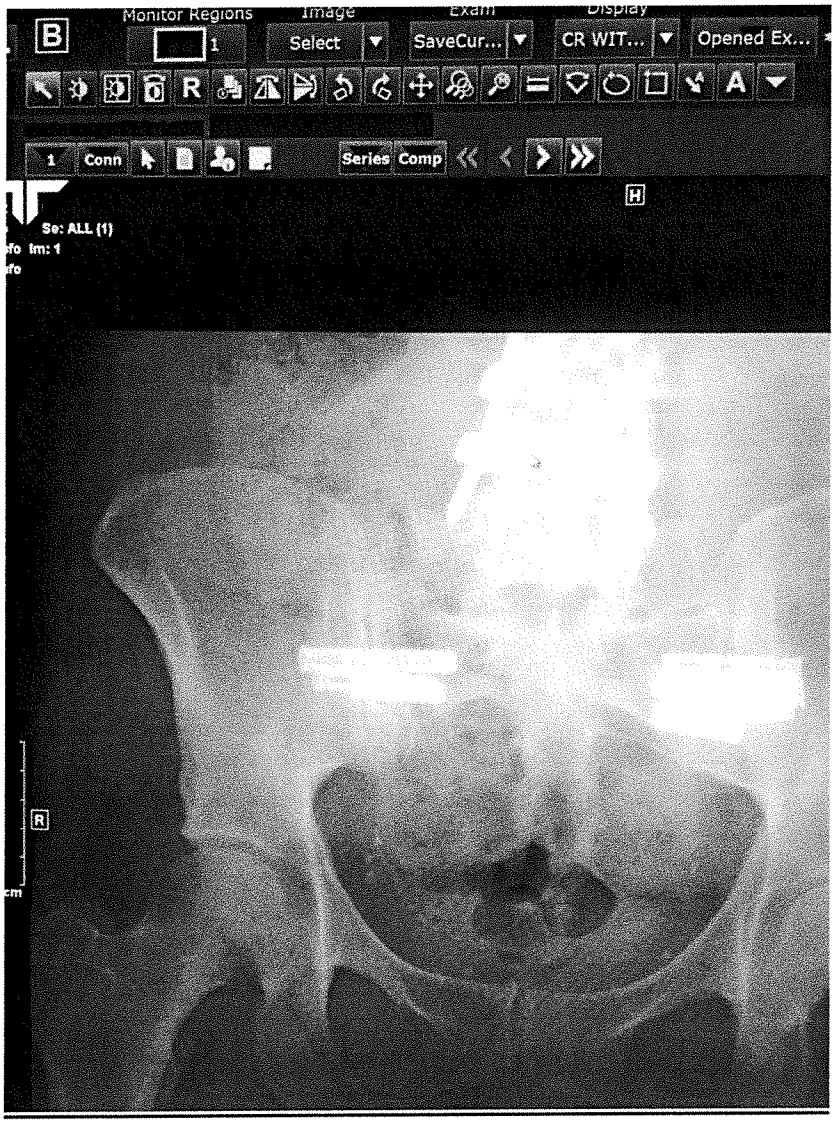


295. Despite her extensive pain as shown, Dr. Asfora states that if a right SI injection provides temporary benefit, she will be set up for bilateral SI fusion and he also states that her previous left SI fusion has likely failed to have bone fusion with the prior implants that he used and he decides to use his Samba Screws in an off-label manner, placing them on the left and right at the same surgical setting.

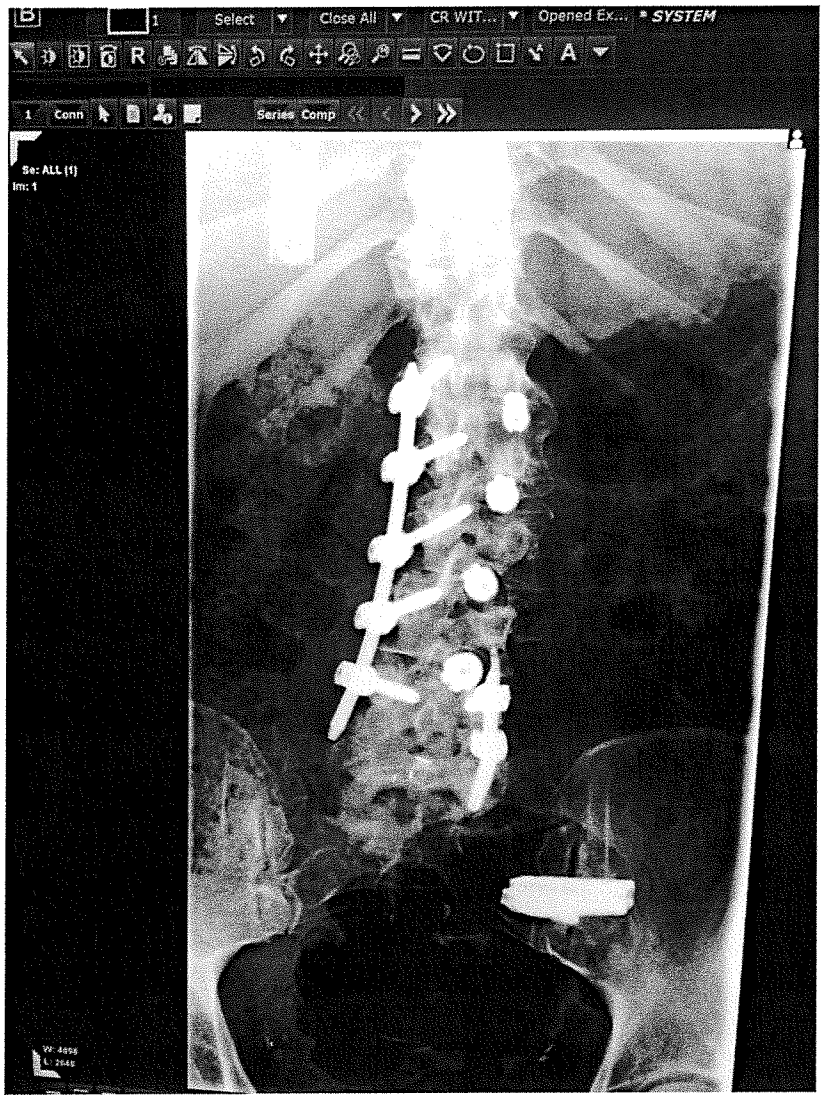
296. Imaging prior to this surgery shows likely failure of fusion across his lumbar fusion sites with clear halo around the left Bullet Cages, a likely source of ongoing left sided pain. At this point, assessment and treatment of a likely failed fusion would be the appropriate step rather than providing more medically unnecessary surgeries in areas that she did not even mention as being painful (but found to be tender with palpation during the exam).

297. Patient[redacted]'s SI fusions are not medically indicated as SI joint pain is not even her area of pain and, even if SI joint pain had been her symptom, the applicable Local Coverage Determination, *supra*, requires far more than pain before this fusion is indicated and reimbursable under Medicare. Furthermore, SI fusion would be contra-indicated based on the criteria: "Absense of generalized pain behavior (e.g., somatoform disorders) or generalized pain disorders (e.g., fibromyalgia)" as evidenced by her pain drawing and ongoing, active treatment for severe, generalized somatic pain.

298. Additionally, a CT scan of the left SI joint after the surgery shows these two added Samba Screws on the left to be doing little to nothing biomechanically as they minimally contact the sacrum. They did not provide any benefit to the patient, but there is never any note in the record of his failed placement of these devices after surgery:



299. Further, the following image shows the obvious halo around the Bullet Cages as likely sources of ongoing pain:



300. In this case, the only benefit of these 5 off-label and not indicated Samba Screw implants being placed was the financial benefit to Dr. Asfora and Sanford as the surgeries were not medically indicated based on the record. Furthermore the patient has obvious dysfunction of her fusion with Bullet Cages placed by Dr. Asfora which he does not choose to follow up on or even mention in the record. This is just a representative example, there are many others similar to this.

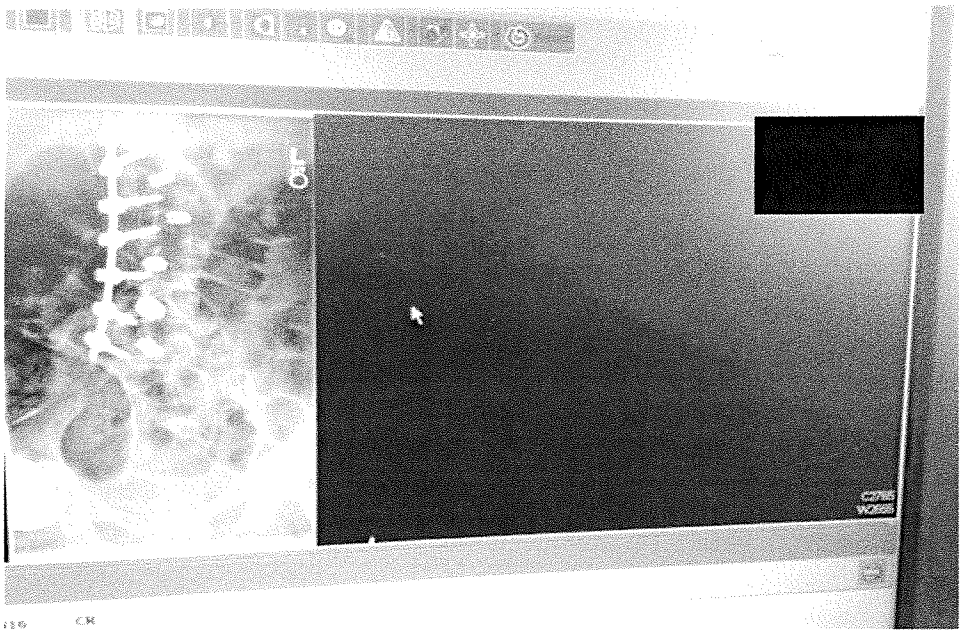
Patient [redacted]

301. As another representative example of the types of medically unnecessary, off-label, not medically indicated and patient safety scenarios Dr. Bechtold routinely sees from Dr. Asfora is Patient [redacted] (DOB: [redacted]/1946), a Medicare patient.

302. Patient [redacted] was operated on by Dr. Asfora on [redacted] 2016, after Dr. Asfora was terminated and then reinstated and with his numerous medically unnecessary surgeries allegedly under review by Sanford management.

303. Dr. Asfora performed a *6-level unilateral fusion* using his Bullet Cages on [redacted] This patient had no indication for needing spinal surgery at all. This surgery was entirely medically unnecessary, off-label and tainted by kickbacks. There is documentation of normal nerve studies and negative response to a spine injection, which further demonstrate no medical necessity for any fusion, let alone a 6-level fusion.

304. The film shows the extensive 6-level medically unnecessary fusion:



305. Patient [redacted] was the last straw causing Dr. Bechtold to pursue this course of action. This patient was first encountered by Dr. Bechtold as an inpatient consultation for a grossly failed right total hip arthroplasty. This was discovered by Dr. Asfora and team immediately after an extensive lumbar fusion with the image included above as a postoperative x-ray obtained in the hospital.

306. Dr. Bechtold did an extensive review of the patient's history and office documentation as part of the consultation, dictated [redacted]/16 at 21:55 and documented in the medical record at 2:20am on [redacted]/16. He also spoke with the patient's daughter who was present for her pre-operative evaluations with whom they believed to be "Dr. Tuntland." (Justin Tuntland, CNP, who is one of Dr. Asfora's PAs).

307. Patient [redacted] history was of a total hip arthoplasty in [redacted] 2011 by an outside provider from Twin Cities Orthopedics. In [redacted] of 2014, she was having increasing pain in that hip and had evaluation by her surgeon. All seemed to be in order at that time but her surgeon had her evaluated by vascular surgery and recommended an MRI of her back to rule it out as a source of her groin pain. She chose to pursue chiropractic care instead, which helped her improve enough to do some travel in Europe, but by [redacted] 2015 she had severe pain in her right hip area.

308. She continued with increasing pain and chiropractic care until seeing Dr. Asfora and team. She described that the pain was largely in her buttock and groin on the right radiating down her lateral and anterior thigh with occasional radiation down into her lower leg. She went from a cane, to a walker, to inability to bear weight through her hip with a sense of instability and inability to trust the use of her leg.

309. She went to the Sanford Neurosurgery Clinic on or about [redacted]/16 and had an evaluation. That note reiterates her symptoms as noted including a large amount of pain consistent with hip pathology as described above. Very little was mentioned to indicate radicular spine symptoms. The patient's daughter and patient reported that Justin Tuntland asked where the worst of her pain had been and what pain she would want taken care of above all else. She and her daughter indicated the pain around the right hip and groin was the worst problem and they report his response to be, "then that's not a problem with your back, that's your hip."

310. Additionally, the note documents absence of EMG/NCS abnormalities as well as an epidural steroid injection with little-to-no relief. There is a documented normal motor exam of the lower extremities with no weakness to indicate nerve root compression.

311. Despite the normal findings documented, and no indications for lumbar spine fusion, there was an offer to do a "right T12-S1 fusion with right pedicle screw placement, but would only provide pt with a 50% chance of improvement of her pain and strength due to the severity of her deformity and her bone quality."

312. At that visit, there is a clearly stated understanding to the patient by Justin Truntland that symptoms are consistent with hip pathology, a large amount of data to confirm absence of spine pathology and a failure to investigate the hip further at all. There also happens to be an x-ray including an obviously failed right total hip arthroplasty obtained at that neurosurgery visit and available at that time.

313. There is no question medically that the hip should have been further evaluated and treated at that time, especially as the treating clinician recognized it as a likely source of

her complaints. Instead, she has a major, extensive unnecessary surgery, which is poorly executed, and which includes six of Dr. Asfora's Bullet Cages.

314. At this point, patient [redacted] has already undergone an unreasonable, medically unnecessary and off-label procedure by a physician with an inherent personal conflict in using his own preference medical devices on her.

315. Already at this point, there are issues of concern including aggressive decision making for fusion with little predicted expectation of relief and without medical indications, but also a failure to adequately assess the patient with a high risk/benefit ratio. Unfortunately, things get worse in this patient example.

316. Patient [redacted] had imaging studies after surgery showing an undeniably failed total hip. Dr. Bechtold's consult note was written in a way as to not directly criticize a fellow surgical employee, but rather to call attention to the absence of good surgical criteria, the failure to investigate the failed total hip or for Dr. Asfora to even address it in the visit or Justin Tuntland to fully document the hip discussion as remembered clearly by the patient's daughter.

317. The surgery was performed [redacted]/16. The operative note is not dictated by Dr. Asfora and transcribed until [redacted]/16, an unusually long time, and also long after the known failed total hip arthroplasty has come to light and Dr. Bechtold's consult note was available.

318. Instead of correctly documenting and forming a plan to address the failed hip issue, Dr. Asfora takes the opportunity to intentionally fabricate the medical record. He attempts to use the consult note written by Dr. Bechtold after the surgery to support or justify his surgical indications.

319. In his post hoc note on [redacted]/16, Dr. Asfora includes the following gross distortion in the INDICATIONS section: "In 2014 this patient started to experience recurrent

right hip pain, as well as severe low back and right sciatica associated with weakness and numbness of her right lower limb. She was seen at the Twin Cities spine center by her original orthopedic surgeon who stated that her hip prosthesis was still in good position and probably not the source of her low back pain and right sciatica. The patient was, therefore, subsequently referred to my service."

320. This is a gross misrepresentation as the patient was not referred to his service for any such symptoms and her previous surgeon had opined 2 years prior that the hip was ok. Imaging at that time in fact does show it to be in good condition. He also had not opined anything regarding sciatica as she was not having those type of symptoms at that time any more than she was at the time of this most recent surgical debacle. The history of the hip was also unknown and undocumented by Dr. Asfora at the time of his surgery and therefore really not part of surgical indications since *he never evaluated the hip.*

321. He continued, stating, "at the time of her visit, we felt that this patient indeed had severe low back pain" (though she notes no back pain at all in that documented visit) and "right sciatica associated with significant weakness" (though documented to be normal in strength exam) and "numbness of her right lower limb" (though numbness was never described or documented in that visit and furthermore nerve conduction studies were normal). Dr. Asfora also wrote, "we also realized this patient had probably some pain radiating from her right hip prosthesis" However, even if this was truthful, which it was not, he therefore knew of this symptom and chose not to investigate further with him already having an image confirming a grossly failed hip available for his review and the symptoms she was most concerned about being all consistent with hip pathology.

322. He also stated in the [redacted]16 note that he told the patient that "any pain generated by her right hip would not be addressed by this surgery" despite her saying that that was the pain that she most wanted fixed. Both the patient and her daughter later state to Dr. Bechtold that there was absolutely no discussion with Dr. Asfora about her hip and that was all a complete fabrication.

323. The issue of this fabrication was brought to the attention of Sanford leadership, including CMO Dr. Wilde, by multiple providers, including Dr. Bechtold. Protecting Dr. Asfora and his lucrative practice, Sanford management told all who brought the issue forward to drop it and they were told that there would be no further response or commentary.

324. At this same time, there were warnings to Dr. Geoff Haft from administration to cease all efforts to look into Dr. Asfora's patients and files, though he had been made aware of this particular patient as part of his duties for surgical case review as brought to his attention by concerned individuals in the hospital trying to bring a gross problem to attention.

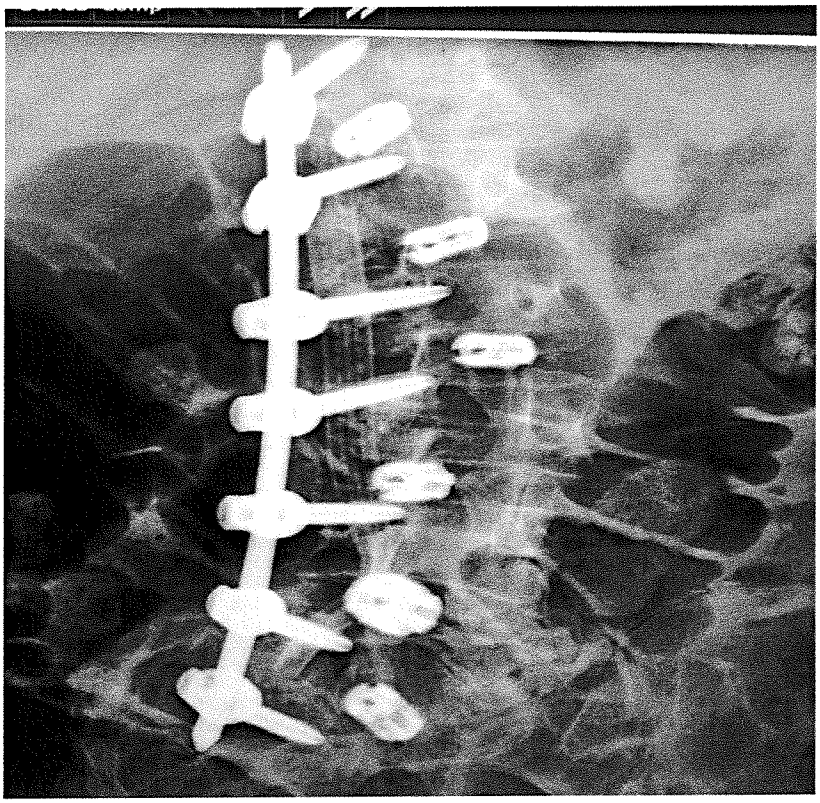
325. Dr. Bechtold personally advised Dr. Wilde of this inappropriate surgery and of Dr. Asfora's choice to document his fabricated surgical indications far after the procedure in direct response to the consultation note and of the egregious error in management. Dr. Bechtold was told in an email from Dr. Wilde on [redacted]2016 that he is "aware of the case you raise. I am not going to share any more information regarding the case."

326. Adding additional concern is the follow up of the patient's spine surgery. A large number of Dr. Asfora's Bullet Cages show lucent lines around the implants highly consistent with failed fusion. Post product surveillance would likely show a high rate of fusion failure for many of his Bullet Cages as seen by Dr. Bechtold during evaluation of patients being seen for concern of hip pathology. It is unclear whether this failure of fusion is due to

chronic poor surgical technique, issues of the implant used, or a combination of both. Any number of patients with continued pain after surgery have clear evidence of this fact, yet the typical evaluation by Dr. Asfora is that the instrumentation is perfect.

327. This patient has a shocking example of this where imaging after surgery shows implants that are clearly doing nothing mechanically, yet are reported to be in good position. [redacted]/16 "Pt seen with Dr. Asfora. We reviewed her lumbar XR which reveals **proper hardware placement**." (Emphasis supplied).

328. The plain x-rays and imaging clearly do not reveal proper placement as they appear to physically move between imaging studies (indicative of a loose implant) and are likely to be a source of ongoing back pain, which the patient did not have prior to the surgery, and which was created by Dr. Asfora's medically unnecessary surgery and failure to attempt any corrective action after the fact. The following is a post-surgery image for this patient:



329. At all times herein, the decisions and actions of Dr. Asfora's clinical staff were made in consultation with him and at his instruction and with his supervision.

330. This is just a representative example, there are many others similar to this.

331. A discernable pattern emerges for Dr. Bechtold as follows: (1) patients go to Dr. Asfora; (2) Dr. Asfora performs medically unnecessary spinal fusion surgery, which puts pressure and pain on the SI joint; (3) when the patient returns post-op with ongoing pain, Dr. Asfora then performs a second SI fusion surgery; (4) when the patient returns post-op with more pain, Dr. Asfora finally refers them to Dr. Bechtold for a hip consult.

332. Continuing the pattern, on many occasions, Dr. Asfora will also insert a pain pump or send the patients for chronic pain management. Many x-rays reviewed by Dr. Bechtold in the context of the hip evaluation show concerning features of the spine surgery

likely contributing to ongoing pain such as Bullet Cages not appearing to even fully contact bone in the disc space. Many of these patients should have never undergone spine surgery or SI fusion in the first place. Others have had hardware shoved into disc spaces or joints with no medically necessity or indication and with no medical benefit. By the time Dr. Bechtold sees these patients, they have had at least 2 medically unnecessary surgeries and sometimes more.

333. A review of all sacroiliac fusion cases performed by Dr. Asfora with his Samba Screws is likely to demonstrate failure to meet published indications for surgery in most, if not all, cases.

Medically Unnecessary and Risky Multiple Level Cases

334. There is little in terms of coverage determinations regarding multiple level fusions because no one other than Dr. Asfora does them for the diagnoses he sees and treats.

335. Relators are unaware of any published, peer-reviewed studies looking at multi-level fusions for non-deformity cases (let alone in the elderly population) because no neurosurgeons or orthopedic spine surgeons outside of the deformity context are routinely doing these surgeries.

336. Moreover, no spinal device or cage has even been approved by the FDA for fusion in more than two levels in the absence of deformity.

337. Further, there is no clinical indication for placing interbody cages into the bone itself. The name "interbody" means "between two bodies," not "in the body" itself. Relator Dr. Wellman, and Drs. Haft and Gust, have never performed or even seen x-rays in their life of a 4, 5 or 6 level fusion in the non-deformity context outside of Dr. Asfora's practice. They trained at very busy medical centers and have more than 60 years of spine surgery experience excluding medical school. Yet, none of them have ever seen another surgeon perform this type

of surgery or seen an x-ray in any way using cages like Dr. Asfora does in numerous multi-level cases in the non-deformity context.

338. However, while there are no coverage determinations relating to indications for multi-level lumbar fusions (because they are not routinely being performed), there an LCD Article regarding documentation in spinal fusion cases that is pertinent and which stresses that general notes in the record regarding failed conservative treatment are improper to justify fusion:

> Medical Necessity
> History and Physical
> - Duration/character/location/radiation of pain
> - Activity of daily living {AOL} limitations
> - Physical examination
>
> **Evidence/support of prior conservative treatment measure(s} attempted**
> Imaging reports pertinent to performed procedure
> Operative report(s}
> Outpatient records before, during and after the procedure that support the medical necessity of performed procedure.
> ***Note: physician statement that conservative treatment measures were completed is not supportive in and by itself;** contractors do require the documentation of these measures.
> ...
> The statement "failed conservative/outpatient treatment" is not sufficient evidence of medical necessity for the procedure or inpatient admission. A detailed medical record will help to support the reasonableness of the claim.
>
> ...

Local Coverage Article: SPINAL FUSION Services: Documentation Requirements (A53973) (Effective date: 10/1/15) (emphasis added).

339. The Local Coverage Article also touches on rare situations in which conservative treatment might not be documented, such as severe cord compression and other emergent situations:

> Situations arise where **a FUSION** is approved without conservative treatment being documented clearly when an emergent situation such as "cauda equina syndrome" is present. Also an imaging report showing severe cord compression, osteophyte formation impinging on the **SPINAL** cord, loose pedicle screws affecting stabillty, severe fibrosis or formation of scar tissue compressing cord or nerves, and the patients history and physical findings correlate to the imaging the surgeon should clearly document these findings and the reasons that such findings require imminent intervention.

Local Coverage Article: SPINAL FUSION Services: Documentation Requirements (A53973) (Effective date: 10/1/15).

340. Further, IASS, The International Society for the Advancement of Spine Surgery, has issued spinal fusion Policy Statements pertinent here as follows:

> **Degenerative Disk Disease in the Elderly.** Lumbar fusion surgery for pure DDD without other co-diagnoses is rare in patients over age 65 and has been poorly studied. Nonetheless, it may be considered an appropriate standard of care in select cases. Lumbar fusion surgery – at a single level – is medically appropriate for elderly patients who meet all the conditions listed above for patients age 25-65.
>
> **Degenerative Disk Disease at Multiple Levels.** Lumbar fusion **surgery at 3 or more levels for pure DDD** in the absence of other co-diagnoses **is considered investigational and is not normally performed in a routine setting**. Likewise, lumbar **fusion surgery at 2 levels in patients over age 65 for pure DDD in the absence of other co-diagnoses is not normally performed**.

Available at: https://www.isass.org/public-policy/isass-policy-statement-on-lumbar-spinal-fusion-surgery/ (*last accessed* 8/2/16). (Emphasis supplied).

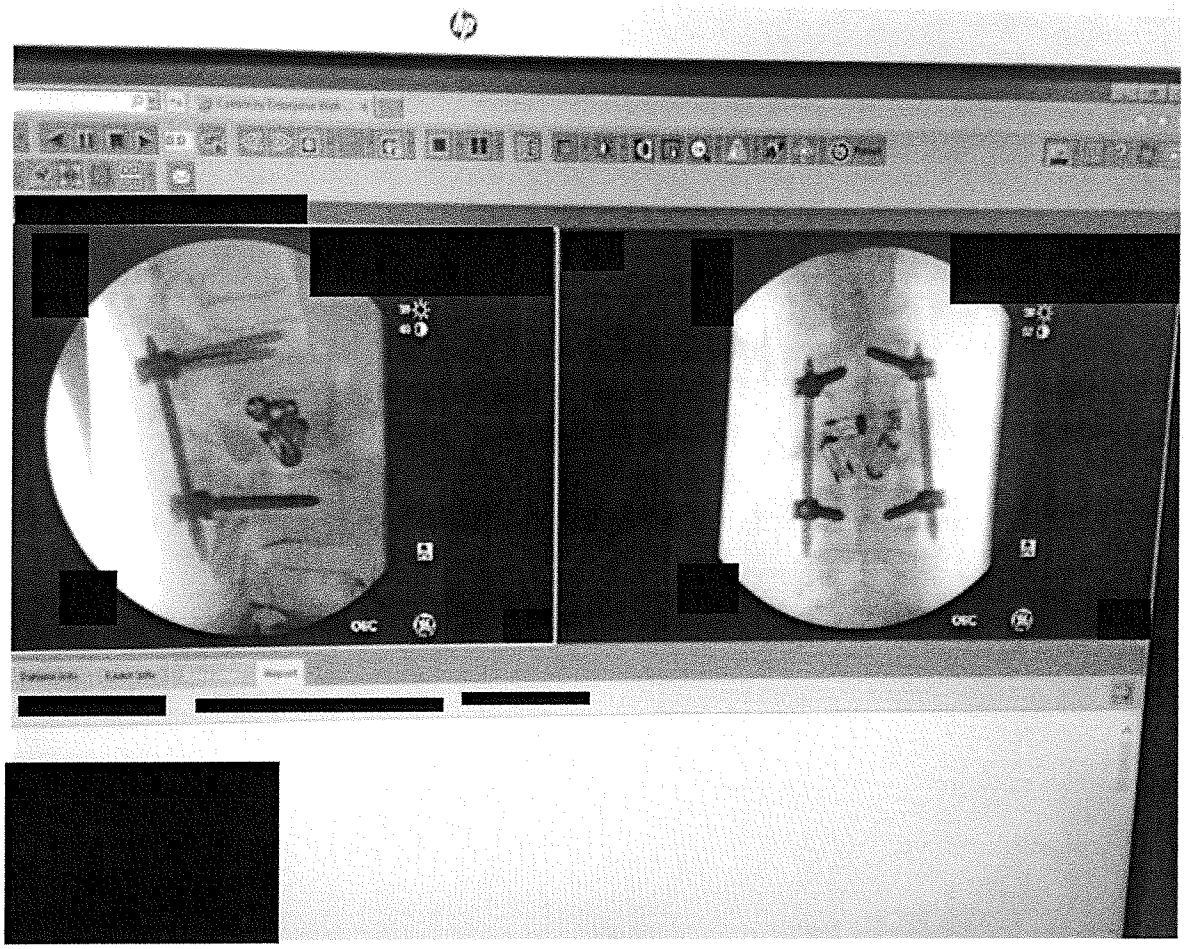
341. Despite medical indications, Policy Statements like that of the ISASS, the medical literature, coverage articles and the standard of care, Dr. Asfora routinely performs multi-level fusions in non-deformity cases on elderly patients without urgent need or medical indication. Moreover, he does so at a personal profit.

Patient [redacted]

342. One representative example of a medically unnecessary and off-label procedure involves patient [redacted] (DOB: 1947). On information and belief, patient [redacted] is a Medicare patient. He was operated on by Dr. Asfora on [redacted] 2011. This patient had an L3 fracture.

343. *No* cages in the vertebral body were medically indicated or necessary for [redacted] Moreover, the Bullet Cage is only indicated for lumbar fusion and not as an interbody device. Regardless, Dr. Asfora implanted *4 Bullet Cages* directly into the bone. This was a medically unnecessary and off-label surgery. It was also an undisclosed kickback.

344. Instead, Dr. Asfora should have braced [redacted]'s fracture and placed screws. A snapshot of his films follows, showing the 4 cages shoved into the bone, not making contact with the adjacent normal bone, not being used for fusion purposes, not medically necessary, and providing no discernable medical benefit to the patient:



345. In addition, his PA entered the OR at the end of surgery and though the PA provided no active assistance, she was billed as an assistant-to-surgery by Dr. Asfora and Sanford for extra revenue from Medicare.

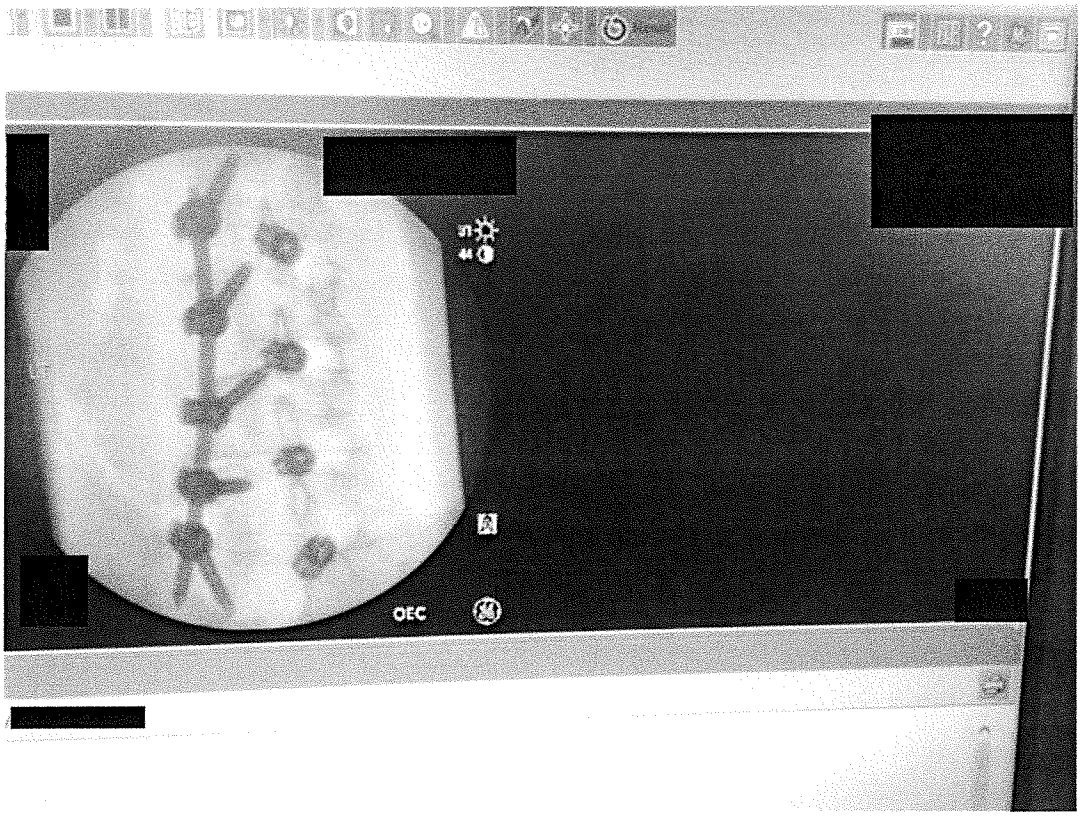
PATIENT [redacted]

346. Another representative example involves patient [redacted] (DOB: [redacted] 1943). Patient [redacted] was operated on by Dr. Asfora on [redacted] 2015. Upon information and belief, he is a Medicare patient. Dr. Asfora performed a 4-level unilateral fusion using his Bullet Cages on this patient.

347. One level is all that was medically necessary for this patient. Dr. Asfora put in three additional cages, which this patient did not need, but which Dr. Asfora personally benefitted from financially. Dr. Asfora never saw this patient prior to surgery. Three of these levels were off-label, medically unnecessary and tainted by kickbacks.

348. Additionally, no PA was ever in the OR during this surgery, but Dr. Asfora and Sanford billed for PA. Michele Healy, regardless, and at an increased cost to the payor. (The Operative Note shows that Dr. Asfora billed for his Physicians' Assistant when the OR log reveals that no PA ever scrubbed in).

349. The patient's scan clearly shows the extensive 4-level off-label and medically unnecessary fusion:

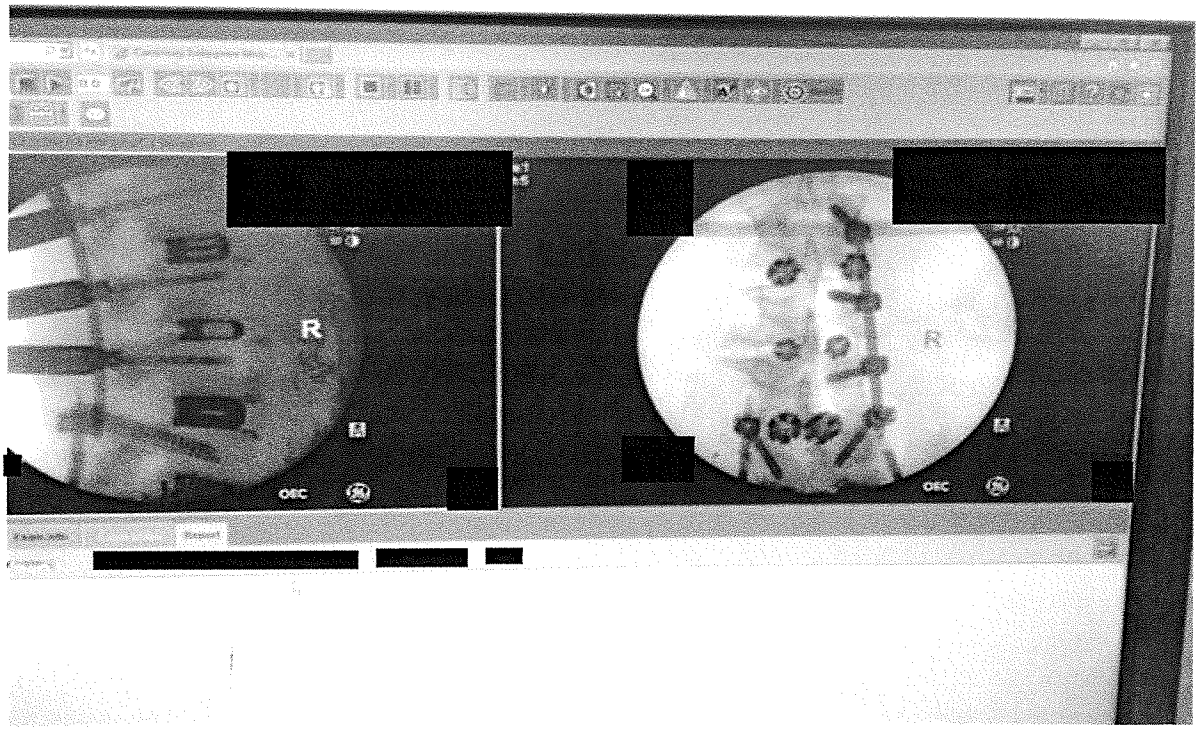


PATIENT [redacted]

350. In another representative example, patient [redacted] (DOB [redacted] 1935) was operated on by Dr. Asfora on [redacted] 2011. Patient [redacted] is a Medicare A/B and Tricare For Life recipient.

351. Dr. Asfora performed a 3-level bilateral fusion, off-label for this device, when only a one level was medically necessary. This procedure was tainted by kickbacks. Dr. Asfora did not see this patient at all before surgery. His PA was in the OR for five minutes, did not scrub in, and did not actively assist, but Dr. Asfora and Sanford billed for the PA for this surgery in order to increase Sanford's reimbursement.

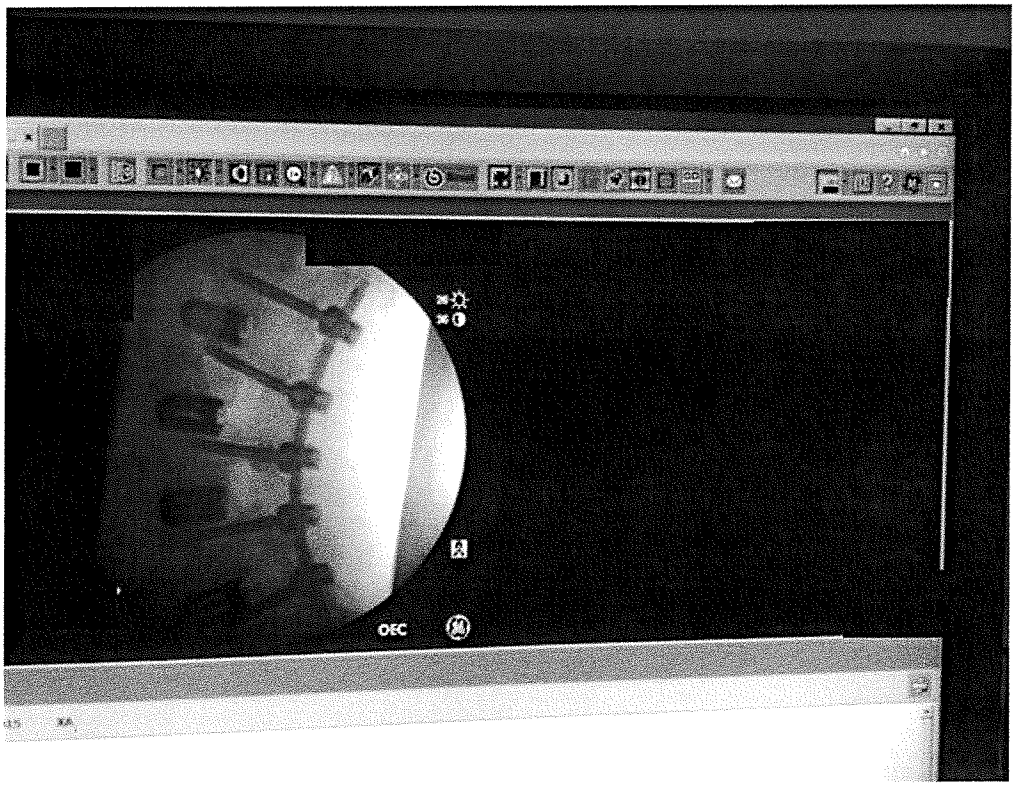
352. The following Patient [redacted] films show the area post-op with the six Bullet Cages clearly visible:



PATIENT [redacted]

353. Another representative example involved Medicare patient [redacted] (DOB [redacted] 1939). Patient [redacted] was operated on by Dr. Asfora on [redacted] 2015. Dr. Asfora performed a 4-level fusion using his Bullet Cages.

354. No spine surgery was indicated for this patient, making the entire surgery medical unnecessary, off-label and non-reimbursable. It was also tainted by kickbacks. The following film clearly shows the extensive four-level fusion:



355. Dr. Asfora also billed for his PA for [redacted]'s surgery when his PA only entered the OR at the very end of the case and performed no active assistance. This was done to increase reimbursement to Sanford and was at its direction and with its knowledge and support.

356. There are many more examples, these are just some representative samples.

Patient harm

357. Dr. Asfora has always performed spine surgery, but the frequency and extreme aggressiveness of his medically unnecessary surgeries changed, not coincidentally, after his Bullet Cage was approved for use.

358. After FDA approval of the device, around 2010, Dr. Asfora greatly increased the medically unnecessary multiple level spine surgeries he performed and has even seemed to be performing more after the covered conduct period of the settlement with the OIG (April 2011).

359. A summary review of Dr. Asfora's files has confirmed this trend. Pre-Bullet Cage approval (before 2010), Dr. Asfora performed approximately 70 instrumented lumber spine surgeries at Sanford and implanted about 142 cages. He performed 7% bilateral and no bilateral cases in multi-level cases. 18 cases were unilateral, multi-level 3, 4 and 5 level cases in this pre-Bullet Cage sample.

360. The year following the release of the Bullet Cage, his numbers and his practice changed radically. He performed approximately 130 instrumented lumbar spine surgeries at Sanford and implanted about 394 Bullet Cages. He increased from 7% bilateral to 49% bilateral with 45 multi-level 3, 4, 5, level case.

361. To confirm that the post-Bullet Cage increase continued, Dr. Asfora's charts were reviewed for six months in 2015 and that data was annualized as follows: he had 144 cases, implanted 386 cages and performed 65% bilateral fusions. Totals for the select, reviewed data follow:

	Pre-Bullet Cage	Immediately Post-Bullet Cage	6 mos. 2015 (annualized)
# of cases	70	130	144
# of cages implanted	142	394	386
% bilateral	7%	49%	65%

362. It is clear that based on any of these measures (number of cages implanted, percentage of bilateral fusions, or number of multi-level fusions), Dr. Asfora's practice greatly changed after the Bullet Cage became available:

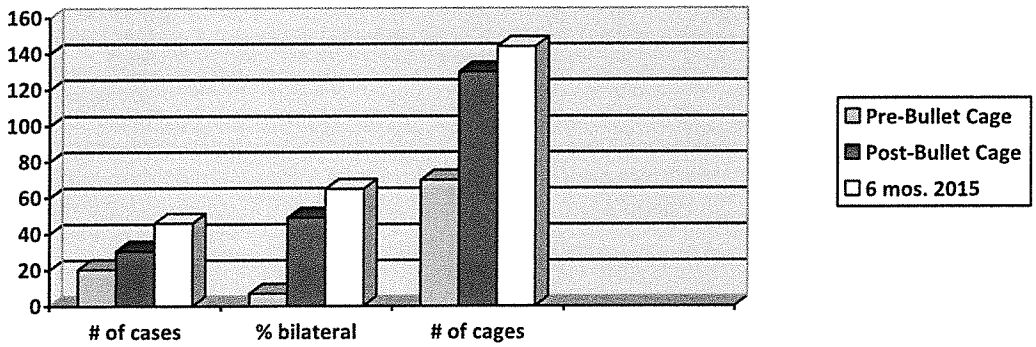


Figure 1 Dr. Asfora summary review.

363. After approval, he increased dramatically the four- and five-level cases he performs. He also now uses the device in uses for which it was never intended. When not implanting four or five cages in a fusion, he will use them as vertebral body devices, far from the posterior lumbar interbody fusion use for which they were approved, and not a medically necessary or indicated use under any circumstance.

364. With the personal financial incentive inherent in using his own device, Dr. Asfora has become brazen and extremely reckless, often performing medically unnecessary surgeries and risking patient well-being.

365. The majority of Dr. Asfora's spine patients are elderly Medicare recipients. The typical patient for him now is an elderly patient who presents with pain in his or her hip or back.

366. Dr. Asfora does not routinely see his patients pre-operatively. He instead has his patients seen and evaluated by his PA's. His PA's then recommend and schedule the patients for spine surgery after Dr. Asfora reviews the patient's x-rays. Many times, Dr. Asfora sees his patients for the first time on the OR table when he is implanting his Bullet Cage in a medically unnecessary and off label way in multiple spinal levels. Many patients report never seeing him after the surgery as well.

367. In summary, Dr. Asfora routinely implants his own Bullet Cages on patients that no physician ever evaluated, in more levels than they need, and in more levels than for which his cage is indicated by the FDA, all due to his inherent conflict as the sole owner and profiteer of the Bullet Cage.

368. A large portion of his surgeries are medically unnecessary as performed because: (1) he either performs surgery on patients for whom spine surgery is not at all indicated; (2) he performs multi-level fusion when only one or two levels are medically necessary and indicated; (3) he performs a medically unsound and unnecessary procedure whereby he implants the fusion device as a vertebral body; and/or (4) he performs fusions when a less extensive, less invasive option, like a microdisectomy, is the only treatment medically necessary and indicated.

369. All of these common improper surgeries by Dr. Asfora risk patient harm. As a consequence, Dr. Asfora has had two wrong level surgeries in the last few months and one instance of a patient developing paralysis. He also has performed medically unnecessary surgeries on a patient with blood clots. And, while all physicians can make mistakes, Dr. Asfora's negative outcomes were never communicated to the patients and are always covered up and intentionally concealed by Sanford, which continues to protect him and profit off of him.

370. In fact, in order to hide his medical error recently, Dr. Asfora fabricated the medical record for both wrong level cases he performed. He falsified the medical record after the wrong level mistake was discovered. In a meeting on September 24, 2015, CMO Dr. Wilde admitted to Drs. Wellman, Gust and Haft that Dr. Asfora had engaged in a "cover up," and that Dr. Wilde had personally reached that conclusion. As to the two wrong level surgeries, Dr. Wilde stated:

> "There's these two cases, which are wrong site surgeries, which in my opinion are pretty clear cut, as a general internist let alone a surgeon. The second one in particular has an issue I think, a big issue of professionalism, where he made a mess and he tried to cover it up, and it's pretty obvious in my opinion."

371. In addition, Dr. Wellman reported this to Sanford's patient relations, which did nothing, and so the patient risk and harm continues. It is not known if the patients were ever advised of the medical error. Both of these cases were ultimately reviewed in peer review, which recommended his termination. No discipline of Asfora followed from Sanford despite assurances that it would.

372. In addition to these negative patient outcomes, for the patients Dr. Bechtold sees, he concludes that they are often not being helped, but are being harmed, by Dr. Asfora's

needless surgeries, which many times require multiple follow-up procedures to attempt to correct. In those instances, the patients are *never* told that the fusion surgery was not necessary, was not indicated for so many levels, was off-label, was a result of a conflict of interest and kickback, and did not help, but harmed, them. The patients are never told that their surgeon owns the device he is implanting against indication and in an unnecessary way in them.

373. These medically unnecessary procedures continue and will continue unabated, unchecked and unsupervised – all to the harm of the patients. Sanford continues to consciously and intentionally protect Dr. Asfora and line its own pocket while putting patients in harm's way.

COUNT 1
FALSE CLAIMS ACT
(Violation of 31 U.S.C. § 3729(a)(1)(A))

374. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

375. This is a claim brought by Relators and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. § 3729 *et seq.*

376. The Federal False Claims Act, 31U.S.C.§ 3729(a)(l)(A), provides:

> Liability for certain acts. Any person who--
> (A) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval ....

Id.

377. By virtue of the above-described acts, including the unreasonable, not medically indicated and medically unnecessary surgeries and the fabricated medical records, among others, since May 2011, Defendant Sanford knowingly presented, or caused to be presented,

false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 31 U.S.C. § 3729(a)(l)(A).

378. In addition, since May 2011, Defendants Asfora and Medical Designs have knowingly caused to be presented false or fraudulent claims for payment or approval, and continue to do so, directly or indirectly to officers, employees or agents of the United States in violation of 31 U.S.C. § 3729(a)(l)(A).

379. In addition, the AKS, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the AKS is an express condition of eligibility and payment of a claims submission for reimbursement under Medicare.

380. By engaging in the fraudulent and illegal practices and conduct alleged herein, including but not limited to the relationship between Dr. Asfora and his PODs and the misuse, overuse and medically unnecessary procedures those relationships result in, among other things, Dr. Asfora and Medical Designs violated the AKS.

381. Defendant Sanford knew about this relationship and its consequences, including medically unnecessary procedures and patient harm, and it allowed it to continue, protected and encouraged it, allowed it to flourish and it continues to benefit therefrom.

382. Defendants' material violations of the AKS led to the presentation to Medicare and its agents' claims for devices and procedures unlawfully tainted by Dr. Asfora's conflicted

relationship, who was paid kickbacks for every Medical Designs device which he implanted and then presented those tainted claims to Medicare and other government payers.

383. Sanford and Dr. Asfora also caused the submission of false claims for the off-label use of the Bullet Cages for non-lumbar use or for more than two adjacent levels as indicated in the FDA approval, as detailed above.

384. Defendants also knowingly presented or caused the submission of false or fraudulent claims for Physicians Assistants for Dr. Asfora's surgeries in which they never participated at all or in which they only participated minimally and did not provide meaningful assistance as assistants-at-surgery.

385. The Defendants intended for all of these claims to be paid by the Federal Government health care programs, state health care programs, and other government payers.

386. Each of the claims that Defendants submitted or caused to be submitted for each procedure done on each patient is a separate, false and fraudulent claim.

387. Defendants presented or caused these claims to be presented with actual knowledge of their falsity, or in deliberate ignorance or reckless disregard that such claims were false for medical devices and uses that were not approved, were off-label, were used for medically unnecessary surgeries, were the results of illegal kickbacks and for PAs who did provide meaningful surgical assistance.

388. For those claims that Defendants submitted or caused to be submitted, it was foreseeable, and in fact the intended result, that those claims would be paid.

389. Further, at all times relevant to this herein, each Defendant acted with the requisite scienter.

390. Such conduct constitutes a violation of the False Claims Act, 31 U.S.C.

§ 3729(a)(I).

391. The United States and the State of South Dakota were unaware of the fraud and fraudulent schemes detailed herein and but for Relators' disclosure, would not have discovered it and its true breadth, scope and harm.

392. The fact and amounts of the false or fraudulent claims to the United States was material. These claims should not have been paid at all by Federal or state health care insurers, or in the alternative, payments should have been limited since the medical devices were being used off-label for the manufacturers benefit, since the surgeries were medically unnecessary, since the PAs did not provide meaningful assistance, and since the claims submitted were the results of, and were each tainted by, an intentional kickback scheme.

393. As a result of these false or fraudulent claims submitted or caused to be submitted by Defendants, the United States Treasury, through Medicare, Medicaid and other federal and state health care programs' payments of these claims, has suffered damage in an amount to be determined at trial, believed to exceed ten millions dollars, plus a civil penalty of $5,500 to $11,000 for each such false claim presented or caused to be presented by Defendants.

COUNT 2
FALSE CLAIMS ACT
(Violation of 31 U.S.C. § 3729(a)(1)(B))

394. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

395. This is a claim brought by Relators and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. § 3729 *et seq.*

396. The Federal False Claims Act, 31 U.S.C. § 3729(a)(l)(B) provides:

> Liability for certain acts. Any person who--
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim ...

397. For purposes of obtaining reimbursement or aiding and assisting to obtain payment or approval of Medicare, Medicaid, or other federal health care programs, Defendants Sanford and Dr. Asfora made or presented or caused to be made or presented false or fraudulent records to the United States, knowing these records to be false or fraudulent or acting with reckless disregard or deliberate ignorance thereof, and it continues to do so, all in violation of 31 U.S.C. § 3729(a)(1)(B).

398. Also, by virtue of the kickbacks, misrepresentations, fabrications, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented misleading and false or fraudulent claims for payment or approval to the Federally funded Medicare Program and other federal and state health care programs and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

399. The claims Defendant submitted or caused to be submitted failed to disclose the underlying violation of the AKS and/or affirmatively misrepresented that the clams were made in compliance with all applicable laws, including the AKS.

400. For those records and/or statements that Defendants made or used or caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment of false reimbursement claims.

401. Further, at all times relevant hereto, Defendants acted with the requisite scienter.

402. Such conduct constitutes a violation of the False Claims Act, 31 U.S.C. § 3729(a)(2).

403. The United States was unaware of the fraud and fraudulent schemes detailed herein and but for the disclosure by these Relators, would not have discovered it and its true breadth and scope.

404. In reliance on the false and fraudulent records presented or caused to be presented by the Defendants, the United States authorized payments to be made which greatly enriched the Defendants and which damaged the United States Government.

405. These claims should not have been paid at all by Federal or state health care insurers, or in the alternative, payments should have been limited since the medical devices were being used as a result of tainted kickbacks, were being used in medically unnecessary surgeries, and were being used off-label. Defendants were also fabricated the presence and meaningful assistance of Dr. Asfora's PAs in surgeries.

406. As a result of these false or fraudulent claims submitted or caused to be submitted by Defendants Sanford and Dr. Asfora, the United States paid the claims, resulting in damages to the United States, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendants.

COUNT 3
False Claim Act
(31 U.S.C. § 3729(a)(1)(C))

407. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

408. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits any person from knowingly and willfully offering or paying any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to any person to induce such person to purchase, order, arrange for, or recommend purchasing or ordering any good, service, or item for which payment may be made (in whole or in part) under a federal health care program.

409. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn *et seq.*, prohibits a physician from making a referral that will lead to a claim being submitted for "designated health services" including those at issue here.

410. Dr. Asfora's use and misuse of the Bullet Cages and Samba Screws, ordered from Medical Designs (whether or not through a middle-man) and paid for by Sanford Health, with kickbacks back to Dr. Asfora, violated both the AKS and the Stark Law.

411. Sanford, Dr. Asfora and Medical Designs knew that each Medicare and Medicaid provider is required to enter into a provider agreement with the Government (CMS Form 855A, 855B, or 8551) and that under the terms of those agreements, each Medicare or Medicaid provider certifies that it will comply with all laws and regulations concerning proper practices for those providers. One of the laws included in this certification is the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(B).

412. A Medicare or Medicaid provider's compliance with the provider agreement is a condition of participation and a condition of payment under the Medicare and Medicaid programs.

413. Physicians who receive payments in violation of the Anti-Kickback Statute violate their certifications and are disqualified from receiving payment as part of the Medicare and/or Medicaid programs.

414. As a result of the actions detailed herein and the kickback tainted claims submitted or caused to be submitted by Sanford, it became ineligible to receive payment under the Medicare and Medicaid programs.

415. It was foreseeable, and indeed intended, and Defendants knew that Dr. Asfora, ineligible under the Medicare and Medicaid programs, would submit claims for payment to the Medicare and Medicaid programs for the purchase and use of Medical Designs devices. These claims by physicians were false, and Defendants caused their submission.

416. As set forth in the preceding paragraphs, Sanford conspired with Dr. Asfora and Medical Designs in an illegal kickback scheme to defraud the United States by getting false and/or fraudulent Medicare and Medicaid claims paid in violation of 31 U.S.C. § 3729(a)(1)(C).

417. Sanford, by and through its officers, agents and employees, authorized and encouraged its various officer agents and employees to take the actions set forth herein.

418. The United States was unaware of the fraud and fraudulent schemes detailed herein, and but for this disclosure, would not have discovered it and its true breadth and scope.

419. In reliance on the false and fraudulent records presented or caused to be presented by Sanford and Dr. Asfora, the United States authorized payments to be made which greatly enriched Defendants and which damaged the United States Government.

420. These claims should not have been paid at all by Federal or state health care insurers, or in the alternative, payments should have been limited since the medical devices were being used as a result of an illegal kickback scheme.

421. As a result of these false or fraudulent claims submitted or caused to be submitted by Defendants, the United States paid the claims, resulting in damages to the United States, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendants.

COUNT 4
Violations of the Federal False Claims Act, 31 U.S.C. § 3729(a)(l)(G)

422. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

423. This is a claim brought by Relators and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730, for Defendant's violations of 31U.S.C. § 3729 *et seq.*

424. The Federal False Claims Act, 31 U.S.C. § 3729(a)(l)(G), provides:

> Liability for certain acts. Any person who--
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government ...

Id. The term "obligation" means:

> an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship,

> form a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment ...

31 U.S.C. § 3729(b)(3).

425. By virtue of the above-described acts, among others, Defendants knowingly made, used, or caused to be made or used false records or statements, and continue to do so, in violation of 31U.S.C. § 3729(a)(l)(G).

426. Relators, and others as detailed herein, informed Defendant Sanford of the various claims alleged herein, but Sanford never took the required and appropriate steps to cease the fraudulent conduct, satisfy the obligations owed to the United States, refund or return such overpayments, and to inform Medicare of the overbilling, and it instead continues to retain the same without proper notice and reimbursement to the Government.

427. As a result of Defendant's violations of 31 U.S.C. § 3729 (a)(l)(G), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and therefore is entitled to treble damages under the False Claims Act, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each claim.

PRAYER FOR RELIEF

WHEREFORE, Relators pray, on behalf of the United States and themselves, that on final trial of this case, judgment be entered in favor the United States and against Defendants as follows:

A. On the First Cause of Action under the False Claims Act, for the amount of the United States' damages, multiplied as required by law and for such civil penalties as are allowed by law, including, but not limited to, statutory penalties for each violation, attorney's fees and costs;

B. On the Second Cause of Action under the False Claims Act, for the amount of the United States' damages, multiplied as required by law and for such civil penalties as are allowed by law, including, but not limited to, statutory penalties for each violation, attorney's fees and costs;

C. On the Third Cause of Action under the False Claims Act, for the amount of the United States' damages, multiplied as required by law and for such civil penalties as are allowed by law, including, but not limited to, statutory penalties for each violation, attorney's fees and costs;

D. On the Fourth Cause of Action under the False Claims Act, for the amount of the United States' damages, multiplied as required by law and for such civil penalties as are allowed by law, including, but not limited to, statutory penalties for each violation, attorney's fees and costs;

E. For the costs of this action, prejudgment interest, interest on the judgment, attorney's fees and for any other and further relief to which Plaintiff, the United States and Relators may be justly entitled; and

F. That Relators be awarded the maximum amount allowed as a Relators' Share pursuant to §3730(d) of the federal False Claims Act.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, RELATORS hereby demand trial by jury.

Dated: August 11, 2016

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